



Regulatory Control on Medical Devices - A Case Study on Device Recalls by USFDA

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The aim of the case study is to reflect on the FDA regulations on the Medical Devices, aspects of classifying the risk caused by the devices and to study the process of recalls by the companies strategically followed by the regulatory authority. Further, a case study was performed to identify the medical devices that were recalled in the year 2020, to investigate the reason for the recall, the subsequent effects on the system and further actions to rectify the problems. The study emphasized various reasons for the medical devices recalled during the year 2020. It warns the companies and users to follow the conditions strictly during their manufacture and trials which would minimize the errors of the functioning of the medical devices in the merfuture. Also the study alerts the medical practitioners about the precautions and safe instructions to be followed during the installation and utilization of the devices.

Keywords: Medical Devices, Recall and Recall Strategy, USFDA, Degree of Risk, Health Hazard, CFR, FDA Law

The term “recall” means the correction or removal action by the manufacturer to address a problem with a medical device that violates FDA Law. Recalls occur when a medical device is defective, when it could be a risk to health, or when it is both defective and a risk to health. A recall indicates that the medical device needs to be checked, adjusted, or fixed or stopped. In many instances, examples of recalls include Inspecting the device for problems, repairing the device, adjusting settings on the device, re-labeling the device, destroying device, notifying patients of a problem and monitoring patients for health issues.¹ If a company may be aware that there is a problem with a group of products, but it cannot predict which individual devices will be affected. To appropriately address the concern, the company may recall an entire lot, model, or product line.

Who Recalls Medical Devices?

In most cases, a company (manufacturer, distributor, or other responsible party) recalls a medical device voluntarily, if any of its product that violates FDA law by initiating a recall (through correction or removal) and notifies the FDA. Legally, the FDA can require a company to recall a device. This could happen if a company refuses to recall a

device that is associated with significant health problems or death. However, in practice, the FDA has rarely needed to require a medical device recall.²

Role of FDA in the Medical Device Recalls

When the FDA learns of a company’s correction or removal action, it reviews the strategy the company proposes to address the problem, assesses the health hazard presented by the product, determines if the problem violates FDA law, potential violations of FDA requirements, and if appropriate assigns the recall a classification (I, II, or III) to indicate the relative degree of risk as given below:

- (i) Class I: A situation where there is a reasonable chance that a product will cause serious health problems or death.
- (ii) Class II: A situation where a product may cause a temporary or reversible health problem or where there is a slight chance that it will cause serious health problems or death.
- (iii) Class III: A situation where a product is not likely to cause any health problem or injury.

Once classified, the FDA monitors the recall to ensure that the recall strategy has been effective. Only after the FDA is assured that a product no longer violates the law and no longer presents a health hazard, does the FDA terminate the recall.

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FDA Notifying the Public about Medical Device Recalls

When a company initiates a correction or removal action, the FDA posts information about the action in the Medical Device Recall Database. The FDA updates the Medical Device Recall Database² after it classifies the recall and again after it terminates the recall. In addition, the FDA may post company press releases or other public notices about recalls, market withdrawals, and safety alerts that may potentially present significant risks to consumers or users of the product. A recall is defined as a method of removing or correcting products that are in violation of laws administered by the Food and Drug Administration (FDA).

Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective. 21 CFR 7 provides guidance so that responsible firms may conduct an effective recall. In rare instances, where the manufacturer or importer fails to voluntarily recall a device that is a risk to health, FDA may issue a recall order to the manufacturer under 21 CFR 810, Medical Device Recall Authority. 21 CFR 810 describes the procedures the FDA will follow in exercising its medical device recall authority under Section 518(e) of the Federal Food, Drug, and Cosmetic Act (Act).³

Under 21 CFR 806, Medical Device Correction and Removals, manufacturers and importers are required to make a report to FDA of any correction or removal of a medical device(s) if the correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the Act caused by the device which may present a risk to health.

Terms in the Context of FDA Decision

(i) **Correction** means repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.

(ii) **Market withdrawal** means a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the FDA or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.

(iii) **Recall** means a firm's removal or correction of a marketed product that the FDA considers to be in

violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. Recall does not include a market withdrawal or a stock recovery.

(iv) **Recall strategy** means a planned course of action to be taken in conducting a specific recall, which addresses the depth of recall, need for public warnings, and extent of effectiveness checks for the recall.

(v) **Recalling firm** means the firm that initiates a recall or, in the case of a Food and Drug Administration-requested recall, the firm that has primary responsibility for the manufacture and marketing of the product to be recalled.

(vi) **Removal** means the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection.

(vii) **Risk to health** means (1) A reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death; or (2) That use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious adverse health consequences is remote.

(viii) **Routine servicing** means any regularly scheduled maintenance of a device, including the replacement of parts at the end of their normal life expectancy, e.g., calibration, replacement of batteries, and responses to normal wear and tear. Repairs of an unexpected nature, replacement of parts earlier than their normal life expectancy, or identical repairs or replacements of multiple units of a device are not routine servicing.³

(ix) **Stock recovery** means the correction or removal of a device that has not been marketed or that has not left the direct control of the manufacturer, i.e., the device is located on the premises owned, or under the control of, the manufacturer, and no portion of the lot, model, code, or other relevant unit involved in the corrective or removal action has been released for sale or use.

Voluntary Recalls - 21 CFR 7

A recall is a method of removing or correcting products that are in violation of laws administered by the Food and Drug Administration (FDA). Recall is a voluntary action that takes place because manufacturers and distributors carry out their

responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective. 21 CFR 7 provides guidance so that responsible firms may conduct an effective recall.³

A recall is an alternative to an FDA-initiated court action for removing or correcting violative products that have been distributed. 21 CFR 7 sets forth specific recall procedures for FDA to monitor recalls and assess the adequacy of a firm's efforts in recall. Recall may be undertaken voluntarily and at any time by manufacturers and distributors, or at the request of the FDA. A request by the FDA that a firm recall a product is reserved for urgent situations and is directed to the firm that has primary responsibility for the manufacture and marketing of the product that is to be recalled. Recall does not include market withdrawal or a stock recovery. A market withdrawal is a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the FDA or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc. Almost all recalls are conducted on a voluntary basis by the manufacturer.

Health Hazard Evaluation

An evaluation of the health hazard presented by a product being recalled or considered for recall is conducted by FDA and takes into account, but need not be limited to, the following factors:

- Whether any disease or injuries have already occurred from the use of the product.
- Whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.
- Assessment of hazard to various segments of the population, e.g., children, surgical patients, pets, livestock, etc., who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.
- Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed.
- Assessment of the likelihood of occurrence of the hazard.

- Assessment of the consequences (immediate or long-range) of occurrence of the hazard.

On the basis of this determination, the FDA will assign the recall a classification, i.e., Class I, Class II, or Class III, to indicate the relative degree of health hazard of the product being recalled or considered for recall.

Classification of the Indices of Health Hazards

Recalls are classified into a numerical designation (I, II, or III) by the FDA to indicate the relative degree of health hazard presented by the product being recalled.

- Class I - a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
- Class II - a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- Class III - a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences^{4,6}.

Recall Strategy

The recalling firm should develop a recall strategy that takes into account the following factors as they apply to the individual circumstances of the particular recall:

- Results of health hazard evaluation.
- Ease in identifying the product.
- Degree to which the product's deficiency is obvious to the consumer or user.
- Degree to which the product remains unused in the market-place.
- Continued availability of essential products.

The FDA will review the adequacy of a proposed recall strategy and recommend changes as appropriate. A recalling firm should conduct the recall in accordance with an approved recall strategy but need not delay initiation of a recall pending review of its recall strategy. A recall strategy will address the following elements regarding the conduct of the recall:

Depth of recall: Depending on the product's degree of hazard and extent of distribution, the recall strategy will specify the level in the distribution chain to which the recall is to extend, as follows:

- (i) Consumer or user level, which may vary with product, including any intermediate wholesale or retail level; or
- (ii) Retail level, including any intermediate wholesale level; or
- (iii) Wholesale level.

Public warning: The purpose of a public warning is to alert the public that a product being recalled presents a serious hazard to health. This is reserved for urgent situations where other means for preventing use of the recalled product appear inadequate. The FDA in consultation with the recalling firm will ordinarily issue such publicity. When the recalling firm decides to issue its own public warning, it is requested to submit to FDA its proposed public warning and plan for distribution of the warning for review and comment. The recall strategy will specify whether a public warning is needed and whether it will issue as:

- (i) General public warning through the general news media, either national or local as appropriate, or
- (ii) Public warning through specialized news media, e.g., professional or trade press, or to specific segments of the population such as physicians, hospitals, etc.

Effectiveness checks: The purpose of effectiveness checks is to verify that all consignees (at the recall depth specified by the strategy) have received notification about the recall and have taken appropriate action. Consignees may be contacted by personal visits, telephone calls, letters, or a combination thereof. A guide entitled "Methods for Conducting Recall Effectiveness Checks" that describes the use of these different methods is available from FDA. The recalling firm will ordinarily be responsible for conducting effectiveness checks, but FDA will assist in this task where necessary and appropriate. The recall strategy will specify the method(s) to be used for and the level of effectiveness checks that will be conducted, as follows:

- (i) Level A--100 percent of the total number of consignees to be contacted;
- (ii) Level B--Some percentage of the total number of consignees to be contacted, which percentage is to be determined on a case-by-case basis, but is greater than 10 percent and less than 100 percent of the total number of consignees;

- (iii) Level C--10 percent of the total number of consignees to be contacted;
- (iv) Level D--2 percent of the total number of consignees to be contacted; or
- (v) Level E--No effectiveness checks.

Firm-Initiated Recall

A firm may choose to remove or correct a distributed product for any reason and under any circumstance. If a firm does this because it believes its product is violative, it is required to immediately notify the FDA by contacting FDA's Office of Regulatory Affairs (ORA) Division Recall Coordinator (DRC). Foreign manufacturers and importers must contact the DRC where their US agent is located. Such removal or correction will be considered a recall only if the FDA determines the product is violative.

In such cases, the FDA will enquire the firm to provide this information:

1. Identity of the product involved.
2. Reason for the removal or correction and the date and circumstances under which the product deficiency or possible deficiency was discovered.
3. Evaluation of the risk associated with the deficiency or possible deficiency.
4. Total amount of such products produced and/or the time span of the production.
5. Total amount of such products estimated to be in distribution channels.
6. Distribution information, including the number of direct accounts and, where necessary, the identity of the direct accounts.
7. A copy of the firm's recall communication if any has issued, or a proposed communication if none has issued.
8. Proposed strategy for conducting the recall.
9. Name and telephone number of the firm official who should be contacted concerning the recall.

The FDA will review the information submitted, advise the firm of the assigned recall classification, recommend any appropriate changes in the firm's strategy for the recall, and advise the firm that its recall will be placed in the weekly FDA Enforcement Report. Pending this review, the firm need not delay initiation of its product removal or correction.

A firm may decide to recall a product when informed by the FDA that the agency has determined that the product in question violates the law, but the agency has not specifically requested a recall. A firm

that initiates a removal or correction of its product which the firm believes is a market withdrawal should consult with its DRC if the reason for the removal or correction is not obvious or clearly understood but where it is apparent, e.g., because of complaints or adverse reactions regarding the product, that the product is deficient in some respect. In such cases, the FDA will assist the firm in determining the exact nature of the problem.

Recall Letter

A recalling firm is responsible for promptly notifying each of its affected direct accounts about the recall. The format, content, and extent of a recall communication should be commensurate with the hazard of the product being recalled and the strategy developed for that recall. In general terms, the purpose of a recall communication is to convey:

- That the product in question is subject to a recall.
- That further distribution or use of any remaining product should cease immediately.
- Where appropriate, that the direct account should in turn notify its customers who received the product about the recall.
- Instructions regarding what to do with the product.

A recall communication can be accomplished by telegrams, mailgrams, or first class letters conspicuously marked, preferably in bold red type, on the letter and the envelope: "medical device recall [or correction]". The letter and the envelope should be also marked: "urgent" for Class I and Class II recalls and, when appropriate, for Class III recalls. Telephone calls or other personal contacts should ordinarily be confirmed by one of the above methods and/or documented in an appropriate manner. A recall communication should be written in accordance with the following guidelines:

- (i) Be brief and to the point;
- (ii) Identify clearly the product, size, lot number(s), code(s) or serial number(s) and any other pertinent descriptive information to enable accurate and immediate identification of the product;
- (iii) Explain concisely the reason for the recall and the hazard involved, if any;
- (iv) Provide specific instructions on what should be done with respect to the recalled products; and
- (v) Provide a ready means for the recipient to report to the recalling firm whether it has any of the

product, e.g., by sending a postage-paid, self-addressed postcard or by allowing the recipient to place a collect call to the recalling firm.^{7,8}

The recall communication should not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message. Where necessary, follow-up communications should be sent to those who fail to respond to the initial recall communication. A recalling firm is encouraged to discuss the recall letter with its DRC prior to issuing the notification. Consignees that receive a recall communication should immediately carry out the instructions set forth by the recalling firm and, where necessary, extend the recall to its consignees in accordance with the instructions described above.

Recall Status Reports

The recalling firm is requested to submit periodic recall status reports to the its DRC so that the agency may assess the progress of the recall. The frequency of such reports will be determined by the relative urgency of the recall and will be specified by the FDA in each recall case; generally the reporting interval will be between 2 and 4 weeks. Unless otherwise specified or inappropriate in a given recall case, the recall status report should contain the following information:

- (i) Number of consignees notified of the recall, and date and method of notification.
- (ii) Number of consignees responding to the recall communication and quantity of products on hand at the time it was received.
- (iii) Number of consignees that did not respond (if needed, the identity of non responding consignees may be requested by the Food and Drug Administration).
- (iv) Number of products returned or corrected by each consignee contacted and the quantity of products accounted for.
- (v) Number and results of effectiveness checks that were made.
- (vi) Estimated time frames for completion of the recall.

Recall status reports are to be discontinued when the recall is terminated by FDA.

Termination of a Recall

A recall will be terminated when FDA determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall

strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. Written notification that a recall is terminated will be issued by its DRC to the recalling firm. A recalling firm may request termination of its recall by submitting a written request to its DRC stating that the recall is effective in accordance with the criteria set forth, and by accompanying the request with the most current recall status report and a description of the disposition of the recalled product.

Public Notification of Recall

FDA publishes a weekly FDA Enforcement Report that contains all enforcement actions including recalls, field corrections, seizures, and injunctions.

Additional Guidance on Recalls

A recall can be disruptive of a firm's operation and business, but there are several steps a firm can take in advance to minimize this disruptive effect. Notwithstanding similar requirements under the Quality System regulation (21 CFR 820), the firm should take into consideration:

- (i) Prepare and maintain a current written contingency plan for use in initiating and effecting a recall in accordance with 21 CFR 7.
- (ii) Use sufficient coding of regulated products to make possible positive lot identification and to facilitate effective recall of all violative lots.
- (iii) Maintain such product distribution records as necessary to facilitate location of products that are being recalled. Such records should be maintained for a period of time that exceeds the shelf life and expected use of the product and is at least the length of time specified in other applicable regulations concerning records retention.

Having these procedures in place prior to the initiation of any recall will allow the recall process to proceed in an efficient manner.

Mandatory Device Recalls - 21 CFR 810

Medical device recalls are usually conducted voluntarily by the manufacturer under 21 CFR 7. In rare instances, where the manufacturer or importer fails to voluntarily recall a device that is a risk to health, FDA may issue a recall order to the manufacturer under 21 CFR 810, Medical Device

Recall Authority. 21 CFR 810 describes the procedures the FDA will follow in exercising its medical device recall authority under section 518(e) of the Federal Food, Drug, and Cosmetic Act (Act).

If, after providing the appropriate person with an opportunity to consult with the agency, FDA finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, the FDA may issue a cease distribution and notification order requiring the person named in the order to immediately:

- (i) Cease distribution of the device;
- (ii) Notify health professionals and device user facilities of the order; and
- (iii) Instruct these professionals and device user facilities to cease use of the device.

The person named in the order will have an opportunity for a regulatory hearing or to provide a written request to FDA asking that the order be modified, vacated, or amended. FDA may later amend the order to require a recall of the device.⁹

Corrections and Removals - 21 CFR 806

Under 21 CFR 806, Medical Devices; Reports of Corrections and Removals, manufacturers and importers are required to make a report to FDA of any correction or removal of a medical device(s) if the correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the act caused by the device which may present a risk to health. A report must be made even if the event was caused by use error. A report is not required if the information has already been provided to FDA under Medical Device Reporting (21 CFR 803) or

Repurchase, Repairs or Replacement of Electronic Products (21 CFR 1004) or if the corrective or removal action was initiated by an FDA order under Medical Device Recall Authority (21 CFR 810). Manufacturers and importers must keep records of those corrections and removals that are not required to be reported to FDA. However, if a report is not required under 21 CFR 806, the firm may voluntarily report under 21 CFR 7. The definition of "risk to health" under 21 CFR 806 tracks the definitions of Class I and Class II recalls in 21 CFR 7.3(m). Therefore, reports of corrections and removals are required for Class I and Class II recalls. Under 21 CFR 806, manufacturers and importers need not report events categorized as Class III recalls under 21 CFR §7; only record keeping requirements would apply.

The following actions are exempted from the reporting requirements:

Actions taken by device manufacturers or importers to improve the performance or quality of a device but that do not reduce a risk to health posed by the device or remedy a violation of the act caused by the device,

- (i) Market withdrawals,
- (ii) Routine servicing, and
- (iii) Stock recoveries

Reporting Conditions

Manufacturers and importers are required to report a correction or removal of a product if it involves a risk to health. Only the person that initiates the correction or removal is required to report. The report must be submitted to FDA within 10 working days from the time the firm initiates the correction or removal. If there is not a "risk to health" involved, a report to FDA is not required, but the manufacturer or importer must keep a record of the correction or removal.

Reporting Requirements as Guided in 21CFR Part 806.10(c):

- (i) Registration number, date the report is made, sequence number (001, 002, etc.), "C" for Correction or "R" for Removal.
- (ii) Name, address, phone number, and contact person of the firm responsible for conducting the correction or removal.
- (iii) Brand name and common name of the device and intended use.
- (iv) FDA marketing status, i.e., 510(k), PMA, pre-amendment status and device listing number^{4,5}.
- (v) Model/catalog number, lot/serial number
- (vi) Manufacturer’s contact information (name, address, phone number, contact person) if different from item #2 above.
- (vii) Description of event(s) and the corrective and removal actions that have been, and are expected to be taken.
- (viii) Any illness or injuries that have occurred with the use of the device. If applicable, include any Medical Device Report (MDR) numbers submitted under 21 CFR 803.
- (ix) The number of devices subject to the Correction or Removal.
- (x) Date of manufacture or distribution; expiration date or expected life.

- (xi) Name, address, and telephone number of all consignees (domestic and foreign) and the dates and number of devices distributed to each consignee.
- (xii) A copy of all communications regarding the correction or removal.
- (xiii) A statement as to why any required information is not available and a date when it will be submitted.

The above requirements are duly filled and submitted to FDA by FDA Electronic Submission Software (eSubmitter) or e-mail.

eSubmitter

Once created, the report is sent to CDRH through the FDA Electronic Submission Gateway (ESG) (following the link: Electronic Submission of 806 Reports of Corrections and Removals).

E-mail

Reports can be mailed to the concerned State's FDA's Office of Regulatory Affairs (ORA) Division Recall Coordinator (DRC). Foreign manufacturers and importers must e-mail the report to the DRC where their US agent is located.⁸⁻¹⁰

Case Study: Identification of Medical Devices Recalled and Strategies followed by the Regulatory Authority during the year 2020

The Aim of the case study is to identify the Medical Devices that were recalled in the year 2020, to analyze the reason for the recall, the subsequent effects on the system and further actions to rectify the problems. This study also lessens the procedures for further approvals in future and also warns about the safety considerations that should be highly prioritized (Table 1 and Fig. 1).¹¹

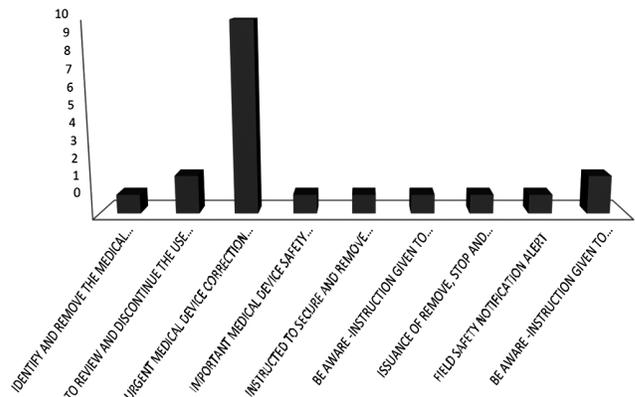


Fig. 1 — Reasons for the USFDA Recalls in 2020

Table 1 — Medical devices recalled in 2020-reasons and further actions

S. No.	Name of the device	Purpose/Category	Reason for the recall	Subsequent affects	Further actions
1	Body guard Infusion pump system	Delivers fluids and medications into a patient's body in controlled amounts	Delay in the therapy due to under-infusion or over-infusion	Serious adverse healthconsequences	Identify and remove any remaining inventory of infusion sets, and discard
2	GlideScope® Core One™ Touch Smart Cable (Video Laryngoscopy)	To provide a clear view of the airway and vocal cords for medical procedures	Potential for temporary or complete loss of image when used with Core 10 and Core 15 video monitors. Ifthere is an interruption in the video signal during use	This may cause the patient to experience serious adverse healthconsequences, including hypoxia and death	Review, locate, discontinue and replacement is notified
3	Arrow Auto CAT®2 andAC3 Optimus®Intra-Aortic Balloon PumpSeries	Cardiac assist devices used with patients undergoingcardiac and non-cardiac surgery, and to treat patients with acute coronarysyndrome or complications from heart failure	Both devices have a part within calledthe MForce motor driver that may break, char, and discolor the motor connector wires. This may lead to pump alarms for "System Error 3" and "High Baseline" presented on the screen of the IABP	The IABP may suddenly stop, even without analarm. This may cause serious patient harm including serious organ damage and death	Immediate check for the device, issuance of urgent medical device correction letter and quarantine the device for inspection procedures
4	Endologix Ovation iX Abdominal Stent Graft System	To treat patients with an abdominal aortic or aortoiliac aneurysms (AAA), a condition that occurs when the body's largest blood vessel (the aorta) becomes stretched and thin, causing the vessel to bulge or expand.Doctors use stent grafts to repair aneurysms and reduce the risk of rupture	Risks of liquid polymer leaks duringimplantation	Liquid polymer may leak into the patient's body.This may cause serious health consequences, including severe allergic type reactions, unstable blood pressure, tissue damage (necrosis), organfailure, cardiac arrest,central nervous system problems, and death	Urgent medical device correction letter and Ovation Field Safety Notice
5	Medtronic Stealth Station	Provides images of a patient's brain to help surgeons navigate surgical tools and implants used during a deep brain stimulation (DBS) procedure	Due to inaccuracies caused by minor patient movements during the auto- registration process when used with NexFrame during a DBS procedure, which may not be detected by the surgeon or the device system	Serious or life-threatening patient harm	Urgent medical device correction letters to all affected patients. FDA is continuing to work with Medtronic to determine whether additional mitigations may be needed
6	Heart Ware HVAD Pump Outflow Graft and Outflow GraftStrain Relief	Help the heart deliver blood tothe rest of the body. The HVAD system is used as abridge to cardiac transplants in patients who are at risk of death from end-stage left ventricular heart failure, forheart tissue recovery, or as destination therapy (DT) in patients where new transplants are not planned	Outflow graft of the HVAD Pump may tear and the strain relief screw may break during assembly prior to implant but might not be observed until during or after the pre-implant pump assembly and attachment to the HVAD pump	Erious patient harm including dizziness, loss of consciousness, bleeding, fluid builduparound the heart, additional medicalprocedures and death	Important Medical device safety alert to all affected customers, Continue to practice standard peri- operative and immediate post-operative patient management to detect for this issue

(contd.)

Table 1 — Medical devices recalled in 2020—reasons and further actions (*contd.*)

S. No.	Name of the device	Purpose/Category	Reason for the recall	Subsequent affects	Further actions
7	Python Embolectomy Catheters, Bard Embolectomy Catheters, and the OTW Latis Cleaning Catheters	Used for temporary blockage, closing of a blood vessel, or infusion of fluids	Risk of the catheter tip detaching during use. If the tip detaches, pieces of the catheter could break off into the patient's body	Potential for serious health consequences including additional surgical procedures to remove the tip, damage to the blood vessel, or death	Urgent: Medical Device Recall Letter to all affected customers
8	Vascular Solutions, Inc. Langston Dual Lumen Catheter	Used for the rapid delivery of dye (contrast material) into a patient's blood vessels during medical imaging tests (angiographic studies) to allow clinicians to see internal body structures. The device also measures pressure within the blood vessel	Potential the inner catheter may separate during use. If the inner catheter separates, it could cause serious health conditions including additional surgical procedures to remove the separated section, damage to the blood vessel or death	If the inner catheter separates outside of the patient's body, the dye could spray the doctor and lead to an infection that may require the doctor to receive treatment	Secure and remove all unused affected devices, Complete the Recall Acknowledgement Form
9	Boston Scientific Corporation IMAGER II 5F Angiographic Catheters	Provide a pathway to deliver contrast agents to blood vessels including carotid arteries	There is a potential for the catheter tip to become detached during a patient procedure or during procedure preparation. Use of the affected product may lead to additional surgical intervention to remove the catheter tip in the patient's blood vessel and increased time in the hospital	Potential for serious adverse events including obstruction of blood flow (embolism), stroke, or death	Remove, stop usage and return
10	Le Maitre Over the Wire Embolectomy Catheter	Indicated for use in the surgical removal of blood clots that are lodged in a blood vessel (emboli) and blood clots that form in the veins (thrombi)	Risk of the balloon catheter failing to deflate during use. If the balloon does not deflate, the tip of the catheter or the balloon could separate and block (obstruct) a patient's blood vessel while the surgeon attempts to remove the inflated balloon catheter	Serious health consequences including additional surgical procedures to remove the tip or balloon pieces, damage to the blood vessel, thrombosis, or death	Urgent medical device recall letters
11	Alaris System Pump Modules	Infusion pump and vital signs monitoring system., deliver fluids, medications, blood and blood products into a patient's body in controlled amounts, provides fluid through an infusion tubing set into a patient's vein or through other cleared routes of administration adult, pediatric and neonatal care	Multiple system errors, software errors, and use-related errors. low battery alarm failures,	Under and over-infusion, with serious injuries and death	Be aware letters sent to all the affected customers

(contd.)

Table 1 — Medical devices recalled in 2020—reasons and further actions (*contd.*)

S. No.	Name of the device	Purpose/Category	Reason for the recall	Subsequent affects	Further actions
12	King VisionVideo Laryngoscope Reusable Adapter	To examine a patient's upper airway and aid in the placement of a tracheal tube. The video adapter connects to the display to show an image. The size ½ video adapter is primarily used in children up to age 10	All devices from the affected lots will show a reversed image on the display. Although the image may appear normal, the user's actions will be reversed on the display for left and right directions. As the defect is not easily detectable, use of the affected video adapter may cause serious adverse health events, including airway trauma and decreased oxygen in your body (hypoxia)	Reversed image may also extend the time to place the trachea tube which may lead to brain damage, organ failure and death	Letters sent not to use
13	Pneumo Dart	To remove air that has become trapped in the pleural cavity during a life threatening situation such as trauma to the lung or a collapsed lung. The needle is used in emergency pre-hospital or hospital settings	The risk of blocked needles. The blockage in the needles is caused by the presence of adhesive from the assembly process. If the needle is blocked, emergency treatment is delayed which can lead to heart or lung failure, or death	An affected device may cause additional injuries since the diagnosis of lung injury may be complicated. If treatment is unsuccessful with the first needle, health care providers may attempt to place another needle and could cause further lung collapse	Urgent Medical Device Recall notice issued
14	Coronary Dilatation Catheter and NCTraveler	To open clogged blood vessels to improve blood flow to the heart	Balloons from the impacted lots may not deflate as intended. This issue is due to weaker material close to the balloon bond resulting from excessive exposure to heat during manufacturing	Use of these devices may cause serious adverse health consequences, such as prolonged cardiac ischemia (reduced blood flow to the heart), air embolism, thrombosis (clot in the artery), myocardial infarction (heart attack), and additional surgery that could lead to post-operative complications, including death	Urgent medical attention letter issued, notice sent to review and return all the unused devices
15	Humidifier Nebulizer Kit	To provide a constant flow of heated and humidified breathing gases to patients. It can be used by neonatal, pediatric and adult patients in health care settings. The system is used with the Neptune Heated Humidifier with Concha Smart Technology and Concha Therm Neptune Heated Humidifier	To the risk for water to flood the column and enter the circuit in the system. If water enters the circuit, water can enter the nose and lungs of the patient	The use of affected product may cause serious adverse health consequences, including low oxygen in the blood (desaturation) and the need for further treatment to prevent long term or serious injury	Urgent Medical Device Recall Notice issued

(contd.)

Table 1 — Medical devices recalled in 2020—reasons and further actions (*contd.*)

S. No.	Name of the device	Purpose/Category	Reason for the recall	Subsequent affects	Further actions
16	Stellar Non-Invasive and Invasive Ventilators	Stellar non-invasive (air pushed through a mask or mouthpiece) and invasive (air pushed through a tube into the windpipe) ventilators are used to provide breathing support to non-ventilator dependent and spontaneously breathing adult and pediatric patients. These devices are used in hospitals, homes, or for mobile use with wheelchairs	The sound alarm may fail to work due to failed electronic part, battery drain for AC, automatic power off	Serious adverse health consequences, including risk of serious injury or death	Field Safety Notification issued to the affected customers
17	MiniMed 600 Series Insulin Pumps	To deliver insulin for the management of their diabetes	Due to a missing or broken retainer ring which helps to lock the insulin cartridge into place in the pump's reservoir compartment, if cartridge is not locked firmly into place, under or over delivery of insulin may occur, which could result in hypoglycemia or hyperglycemia	Severe hyperglycemia can result in a loss of consciousness, seizure, and death.	Customers are notified to examine the retainer ring of the pump and stop usage if damaged.
18	GE Carestation 600 series anesthesia systems	To provide general inhalation anesthesia and breathing support (mechanical ventilation) to pediatric and adult patients environments, such as hospitals, surgical centers, or clinics	Potential for a loose cable connection inside the system which may cause the mechanical ventilation to stop working. If this occurs, the system will emit a high priority audio and visual alarm to alert the health care provider. Loss of mechanical ventilation could lead to low (hypoxia) blood oxygen levels in the patient if the health care provider does not ventilate the patient manually or with an alternate system	The use of the affected product may cause the patient to have low blood oxygen levels, which could result in tissue or organ damage, or death	Safety instructions given to customers
19	Airway Gas Option N-CAiO and Respiratory modules	For use with patient monitors and ventilators to measure respiratory gases (such as oxygen and carbon dioxide), anesthesia, and breathing characteristics in adults, pediatric, and neonatal Patients	May cause the devices to display incorrect oxygen values which could lead to high (hyperoxia) or low (hypoxia) blood oxygen levels in the patient.	The use of the affected product may cause long-term high or low blood oxygen levels, which could result in organ damage, tissue injury, increased chance of infection, or death	Customers were issued letters for their safety during usage, or to get them replaced. FDA warned the patients to clearly observe if the modules are deteriorated

(contd.)

Table 1 — Medical devices recalled in 2020—reasons and further actions (*contd.*)

S. No.	Name of the device	Purpose/Category	Reason for the recall	Subsequent affects	Further actions
20	H2O Pressure Relief Manifold	Used as part of a breathing circuit designed to assist the breathing of infant patients who weigh no more than 10 kilograms	H2O Pressure Relief Manifold does not hold pressure when initially set up on a patient. This issue is due to a dislodged valve not being properly seated, resulting in loss of pressure in the system	Use of the affected devices may cause serious adverse health consequences, including lower blood oxygen levels, slow heart rate, stopped breathing (apnea), rebreathing of exhaled carbon dioxide by the patient and need for medical intervention and resuscitation	Medical Device Recall notice to immediately discontinue and quarantine the device

Conclusion

The FDA posts synopses of evidence about the most serious medical device recalls. These products are on the list because there is a sensible risk that they could cause serious health problems or death. Nearly all medical devices recalled for life threatening or very serious hazards were originally cleared for market using the less stringent 510(k) process or were considered. The present study reveals that most of the medical devices recalled by the FDA in the red to serious risks in 2020 were exempted from regulatory review like in the past. Medical devices cleared through the less rigorous 510(k) pathway comprise more than two-thirds of the products that are recalled by the FDA because they could seriously harm patients or result in death. When devices that were intentionally exempt from any FDA review were added to the 510(k) devices.¹¹ Thus, the standards used to determine whether a medical device is a high-risk or life-sustaining product prior to approval are clearly very different from the standards used to recall a medical device as life threatening. Our findings reveal critical flaws in the current FDA device review system and its implementation that will require either congressional action or major changes in regulatory policy. The results of the present analysis indicate that the number of high-risk recalls of medical devices and the number of patients affected by these recalls would be substantially decreased if the following changes were made in the FDA process: 1. The FDA fully implements current law that subjects “life- saving and life sustaining” (Class III) devices to the PMA process; 2. The FDA’s definition of a high-risk device takes into account the potential risks if the device

fails; 3. The FDA expands the use of their authority to inspect the manufacturing of 510(k) devices just as they do for devices approved through the PMA process; and 4. The FDA strengthens their authority to use special controls for 510(k) devices as they do for PMA devices, such as post market surveillance, performance standards, and product-specific and general guidance documents.

References

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- 2 US Government Accountability Office. FDA should take steps to ensure that high risk device types are approved through the most Stringent P remarket Review Process: GAO-09-190: January 2009, <http://gao.gov/new.items/d09190.pdf>, (accessed on 9 November 2010).
- 3 <https://www.fda.gov/medical-devices/overview-device-regulation/code-federal-regulations-cfr>.
- 4 SEC. 515. [21 USC §360e] Premarket Approval; General Requirement.
- 5 SEC. 515. [21 USC §360e] Premarket Approval; General Requirement.
- 6 21 CFR 814.
- 7 The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles-Final Guidance for FDA and Industry.
- 8 PMA Guidance Documents: USFDA.
- 9 CPG Section 300.750 Class III Devices Subject to 515(b) Requirements.
- 10 Zukerman D M, Brown P & Nissen S E, Medical Device Recalls and the FDA Approval Process, *Arch Intern Med*, 171 (11) (2011)1006-1011, doi:10.1001/archinternmed.2011.30.
- 11 <https://www.fda.gov/medical-devices/medical-device-recalls/2020-medical-device-recalls>.