Report to Congress

Postmarket Device Safety-Related Communications

(Consolidated Appropriations Act, 2023 (Pub. L. No. 117-328))

Executive Summary

The Center for Devices and Radiological Health (CDRH) in the Food and Drug Administration (FDA) is charged with protecting and promoting the public health and ensuring that the over 248,400 different types of medical devices CDRH regulates are safe and effective for patients in the United States. FDA's Center for Biologics Evaluation and Research (CBER) regulates medical devices related to licensed blood and cellular products and devices intended for HIV diagnosis and monitoring.

FDA strives to provide current information concerning the benefits and risks of marketed medical devices to health care providers, patients, and consumers so that they can make informed treatment and diagnostic decisions. When a device safety risk is identified, FDA may address the identified risk through a variety of methods, including sharing information with health care providers, patients, and caregivers. From January 1, 2023, through December 31, 2024, FDA issued 51 device safety-related communications, including 27 CDRH Medical Device Safety Communications (see https://www.fda.gov/medical-devices/medical-device-safety/safety-communications), 23 CDRH Letters to Health Care Providers (see https://www.fda.gov/medical-devices/medical-device-safety/letters-health-care-providers), and 1 CBER Safety and Availability Communication (see https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/2024-safety-and-availability-communications). Of the 51 device safety-related communications issued in 2023-2024, 32 provided new information about device safety, 6 provided new information about recalls that had resolved the problem (e.g., the device was removed from the market), and 13 provided updates to previous communications issued by CDRH.

The most recent device safety-related communications released by CDRH can be found on CDRH's Medical Device Safety website (https://www.fda.gov/medical-devices/medical-device-safety).

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Abbreviation List

Abbreviation	Definition
CBER	Center for Biologics Evaluation and Research
CDRH	Center for Devices and Radiological Health
FDA	Food and Drug Administration
MDR	Medical Device Reports

I. Background

According to its mission statement (https://www.fda.gov/about-fda/what-we-do#mission) the Food and Drug Administration (FDA)

> "is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors."

FDA is composed of several Offices and Centers, including the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER).[1] CDRH is charged with protecting and promoting the public health by ensuring that the over 248,400 different types of medical devices it regulates are safe and effective for patients in the United States. FDA's Center for Biologics Evaluation and Research (CBER) regulates medical devices related to licensed blood and cellular products and devices intended for HIV diagnosis and monitoring.

FDA strives to ensure that patients and providers have timely and continued access to safe and effective medical devices and safe radiation-emitting products. To do so, FDA conducts postmarket surveillance. New information about a device's safety, such as reports of unexpected adverse events, may become available once a device is more widely distributed and used under real-world conditions (e.g., in routine clinical practice, in the home setting, in broader patient populations, and by a broader range of clinicians). In these real-world settings, new safety concerns may be identified. When a device safety risk is identified, FDA may address the identified risk through a variety of methods, including sharing information with health care providers, patients, and caregivers.

Within the scope of FDA's activities to promote and protect the public health, FDA utilizes communication measures to inform health care providers and the public regarding changes in the safety of or the identification of previously unknown risks associated with the use of a given marketed medical device or device type. These communication measures involve communicating with the public about safety concerns; the intent of these public communications is to provide health care providers, patients, and consumers with access to the most current information concerning the performance and potential benefits and risks of marketed medical devices so that they can make

[1] Although medical devices provide benefits to patients, they also present risks. FDA's public health responsibilities span the life cycle of medical devices and, at every stage, FDA must make well-supported regulatory decisions, taking into account the totality of the evidence, to determine whether the benefits outweigh the risks.

informed decisions about their treatment and diagnostic options.

Under section 3307(b) of the Consolidated Appropriations Act, 2023 (Pub. L. No. 117-328), the Secretary of Health and Human Services is charged with the following:

> Not later than September 30, 2023, and biennially thereafter, the Secretary shall submit to the Committee on Health, Education, Labor and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and publish on the website of the Food and Drug Administration, a report on the number of postmarket device signals communications issued by the Secretary, the sources of data for such signals, and how such signals were revised or resolved.

This report is in response to that charge.

II. Device Safety-Related Communications (January 1, 2023 - December 31, 2024)

A. Sources of Data

To ensure the safety and effectiveness of devices once they are on the market, FDA monitors for and addresses device safety risks. FDA uses a multifaceted approach that relies on various methods and techniques under its current authorities. For example, FDA monitors reports of adverse events and other problems with medical devices from a variety of sources, including, but not limited to, medical device reports (MDRs), which are reports of certain adverse events and device malfunctions; reports from MedSun, which is an adverse event reporting program (see https://www.fda.gov/medical-devices/medical-device-safety/medsun-medical-product-safety-network); data from mandated postmarket studies; clinical trials or data published in scientific literature; and epidemiological research, including evaluations of administrative databases, health care claims data or registries, and inquiries or investigations from global, federal, or state health agencies. In addition, FDA seeks information from, or consults with, stakeholders such as external clinical or scientific experts, patients, industry, and other governmental and regulatory agencies.

The device safety-related communications issued by CDRH and CBER during calendar years 2023 and 2024 were supported by information from the following:

- Complaints and allegations;
- Device authorizations;
- Device shortages and supply chain concerns;
- Inspections of device establishments for compliance with quality system and other applicable requirements;
- Laboratory evaluations;
- Mandated postmarket study results (e.g., post-approval study, postmarket surveillance study - also referred to as a 522 study);
- Manufacturer reports of corrections and removals;
- Medical device reports (MDRs);
- Real-world data;
- Review of the scientific literature; and,
- Updates to product labeling.

B. Types of Device Safety-Related Communications

FDA addresses device safety risks in a variety of ways, such as through product recalls and safety-related communications. The following types of safety-related communications inform the public of problems or potential problems with respect to devices that are on the market:

- Medical Device Safety Communications;
- Medical Device Safety and Availability Communications; and,
- Letters to Health Care Providers.

From January 1, 2023, through December 31, 2024, FDA issued 51 device safety-related communications, including 27 CDRH Medical Device Safety Communications (see https://www.fda.gov/medical-devices/medical-device-safety/safety-communications), 23 CDRH Letters to Health Care Providers (see https://www.fda.gov/medical-devices/medical-device-safety/letters-health-care-providers), and 1 CBER Safety and Availability Communication (see https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/2024-safety-and-availability-communications). Of these 51 device safety-related communications issued in 2023-2024:

- Thirty-two provided new information about device safety (Appendix A);
- Six provided new information about device safety recalls that had resolved the problem (e.g., the device was removed from the market) (Appendix B); and,
- Thirteen provided updated information about device safety to previous communications issued by CDRH (Appendix C), including two that provided updated information to safety-related communications issued by CDRH in 2024, four that provided updated information to safety-related communications issued by CDRH in 2023, and seven that updated safety-related communications issued by CDRH prior to 2023.

CDRH takes regulatory or enforcement actions to resolve postmarket problems when appropriate. Generally, CDRH has many avenues it can take to resolve these problems, including:

- Requesting or requiring the manufacturer to remove the device from the market;
- Issuing public communications;
- Conducting inspections;
- Sending advisory action letters to manufacturers and firms marketing the device;
- Issuing guidances;
- Developing standards regarding a particular device area;
- Requiring postmarket surveillance studies; and,
- Upclassification of a device (e.g., reassignment to Class III).

In some cases, CDRH determines that no action is required.

III. Sources Utilized for This Report

The following publicly available sources were utilized in preparing this report:

- Medical Device Safety (https://www.fda.gov/medical-devices/medical-device-safety)
- 2023 Safety Communications (https://www.fda.gov/medical-devices/safety-communications/2023-safety-communications)
- 2023 Letters to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/2023-letters-health-care-providers)
- 2023 Safety and Availability Communications https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/2023-safety-and-availability-communications
- 2024 Safety Communications (https://www.fda.gov/medical-devices/safety-communications/2024-safety-communications)
- 2024 Letters to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/2024-letters-health-care-providers)
- 2024 Safety and Availability Communications https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/2024-safety-and-availability-communications
- CDRH 2024 Annual Report (https://www.fda.gov/about-fda/cdrh-reports/cdrh-2024-annual-report)
- Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health (https://www.fda.gov/about-fda/cdrh-reports/medical-device-safety-action-plan-protecting-patients-promoting-public-health)

IV. Conclusion

At every stage of a device's life cycle, FDA maintains a robust program for evaluating its safety. Ensuring the safety of medical devices on an ongoing basis includes having a vigilant postmarket surveillance system for the timely identification of new or increased safety concerns, sharing timely public communications/notifications about safety concerns when warranted, and addressing concerns through a variety of methods.

The Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health (https://www.fda.gov/media/112497/download) outlines a vision for how CDRH can continue to enhance its programs and processes to ensure the safety of medical devices throughout the total product life cycle. These programs and processes include providing for the timely communication and resolution of new or increased safety issues and advancing innovative technologies that are safer, are more effective, and address unmet needs.

CDRH strives to provide current information concerning the benefits and risks of marketed medical devices to health care providers, patients, and consumers so that they can make informed treatment and diagnostic decisions. The most recent safety-related communications released by CDRH can be found on CDRH's Medical Device Safety website (https://www.fda.gov/medical-devices/medical-device-safety).

Appendix A – CBER's and CDRH's 2023-2024 Device Safety-Related Communications That Provided New Information About Device Safety

Date	Communication	Type
02/27/2023	Abbott Trifecta Valves: Potential Risk of Early Structural Valve Deterioration - Letter to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/abbott-trifecta-valves-potential-risk-early-structural-valve-deterioration-letter-health-care)	Letter to Health Care Provider
03/01/2023	Getinge/Maquet Cardiohelp System: Potential Insufficient Packaging Sterility with HLS Set Advanced - Letter to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/getingemaquet-cardiohelp-system-potential-insufficient-packaging-sterility-hls-set-advanced-letter)	Letter to Health Care Provider
03/23/2023	Risks with Exactech Joint Replacement Devices with Defective Packaging - FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/risks-exactech-joint-replacement-devices-defective-packaging-fda-safety-communication)	Safety Communication
03/30/2023	Evaluation of Safety Concerns with Certain Dental Devices Used on Adults – FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/evaluation-safety-concerns-certain-dental-devices-used-adults-fda-safety-communication)	Safety Communication
04/12/2023	Risk of Protection Failure with Certain O&M Halyard Surgical N95 Respirators, Surgical Masks, and Pediatric Face Masks - FDA Safety Communication	Safety Communication

Date	Communication	Type
	https:/web.archive.org/web/20230414105721/https:/www.fda.gov/medical-devices/safety-communications/risk-protection-failure-certain-om-halyard-surgical-n95-respirators-surgical-masks-and-pediatric	
04/27/2023	Illumina Cybersecurity Vulnerability Affecting the Universal Copy Service Software May Present Risks for Patient Results and Customer Networks: Letter to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/illumina-cybersecurity-vulnerability-affecting-universal-copy-service-software-may-present-risks)	Letter to Health Care Provider
06/05/2023	Non-sterile, Single-use Pneumatic Tourniquet Cuffs Conservation Strategies - Letter to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/non-sterile-single-use-pneumatic-tourniquet-cuffs-conservation-strategies-letter-health-care)	Letter to Health Care Provider
07/17/2023	Do Not Use RoyalVibe Health, CellQuicken, or Well-Being Reality Ultrasound Medical Devices: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/do-not-use-royalvibe-health-cellquicken-or-well-being-reality-ultrasound-medical-devices-fda-safety)	Safety Communication
07/19/2023	Use Alternative Testing Method for the Quidel Cardiovascular Inc. Quidel Triage Cardiac Panel - Letter to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/use-alternative-testing-method-quidel-cardiovascular-inc-quidel-triage-cardiac-panel-letter-health)	Letter to Health Care Provider
08/11/2023	Do Not Use Tests Manufactured by Universal Meditech, Inc.: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/do-not-use-tests-manufactured-	Safety Communication

Date	Communication	Type
	universal-meditech-inc-fda-safety-communication)	
11/09/2023	Labeling Updates for BD Mesh Products - Letter to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/labeling-updates-bd-mesh-products-letter-health-care-providers)	Letter to Health Care Provider
11/20/2023	Do Not Use Cardinal Health Monoject Syringes with Syringe Pumps and PCA Pumps - Letter to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/do-not-use-cardinal-health-monoject-syringes-syringe-pumps-and-pca-pumps-letter-health-care)	Letter to Health Care Provider
11/21/2023	Voluntary Recall of SoClean Equipment Intended for Use with CPAP Devices and Accessories: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/voluntary-recall-soclean-equipment-intended-use-cpap-devices-and-accessories-fda-safety)	Safety Communication
11/28/2023	Carefully Monitor Philips DreamStation 2 CPAP Machines for Signs of Overheating: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/carefully-monitor-philips-dreamstation-2-cpap-machines-signs-overheating-fda-safety-communication)	Safety Communication
11/30/2023	Evaluating Plastic Syringes Made in China for Potential Device Failures: FDA Safety Communication (https://web.archive.org/web/20231204163903/https://www.fda.gov/medical-devices/safety-communications/evaluating-plastic-syringes-made-china-potential-device-failures-fda-safety-communication#main-content)	Safety Communication

Date	Communication	Type
12/27/2023	HSV-2 Tests for Genital Herpes Can Produce False Reactive Results - Letter to Clinical Laboratory Staff and Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/hsv-2-tests-genital-herpes-can-produce-false-reactive-results-letter-clinical-laboratory-staff-and)	Letter to Health Care Provider
01/03/2024	Do Not Use Synovo Total Hip Resurfacing System: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/do-not-use-synovo-total-hip-resurfacing-system-fda-safety-communication)	Safety Communication
01/09/2024	Potential Exposure to Certain Chemicals with Use of GE HealthCare EVair and EVair03 Compressors with Certain Ventilators – Letter to Health Care Providers (https://web.archive.org/web/20240117114831/https://www.fda.gov/medical-devices/letters-health-care-providers/potential-exposure-certain-chemicals-use-ge-healthcare-evair-and-evair03-compressors-certain)	Letter to Health Care Provider
01/16/2024	Risks with Exactech Equinoxe Shoulder System with Defective Packaging - FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/risks-exactech-equinoxe-shoulder-system-defective-packaging-fda-safety-communication)	Safety Communication
01/18/2024	Certain ResMed Ltd Masks for BiPAP, CPAP Machines Recalled Due to Safety Issue with Magnets That May Affect Certain Medical Devices: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/certain-resmed-ltd-masks-bipap-cpap-machines-recalled-due-safety-issue-magnets-may-affect-certain)	Safety Communication

Date	Communication	Type
02/21/2024	Do Not Use Smartwatches or Smart Rings to Measure Blood Glucose Levels: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/do-not-use-smartwatches-or-smart-rings-measure-blood-glucose-levels-fda-safety-communication)	Safety Communication
02/27/2024	BioZorb Markers and Potential Risks with Use in Breast Tissue: FDA Safety Communication (https://web.archive.org/web/20240417004046/https://www.fda.gov/medical-devices/safety-communications/biozorb-markers-and-potential-risks-use-breast-tissue-fda-safety-communication)	Safety Communication
02/29/2024	Hintermann Series H3 Total Ankle Replacement Has a Higher-Than-Expected Risk of Device Failure: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/hintermann-series-h3-total-ankle-replacement-has-higher-expected-risk-device-failure-fda-safety)	Safety Communication
02/29/2024	Follow Instructions for Safe Use of Electrical Operating Room Tables - Letter to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/follow-instructions-safe-use-electrical-operating-room-tables-letter-health-care-providers)	Letter to Health Care Provider
04/22/2024	FDA Encourages the Public to Follow Established Choking Rescue Protocols: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/fda-encourages-public-follow-established-choking-rescue-protocols-fda-safety-communication)	Safety Communication
05/13/2024	UPDATE: Do Not Use Cue Health's COVID-19 Tests Due to Risk of False Results: FDA Safety Communication	Safety Communication

Date	Communication	Type
	(https://www.fda.gov/medical-devices/safety-communications/do-not-use-cue-healths-covid-19-tests-due-risk-false-results-fda-safety-communication)	
07/10/2024	Disruptions in Availability of BD BACTEC Blood Culture Media Bottles - Letter to Health Care Providers (https://web.archive.org/web/20240714162328/https://www.fda.gov/medical-devices/letters-health-care-providers/disruptions-availability-bd-bactec-blood-culture-media-bottles-letter-health-care-providers)	Letter to Health Care Provider
07/31/2024	Safe Use of Megadyne Mega 2000 and Mega Soft Patient Return Electrodes - Letter to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/safe-use-megadyne-mega-2000-and-mega-soft-patient-return-electrodes-letter-health-care-providers)	Letter to Health Care Provider
09/17/2024	Zimmer Biomet CPT Hip System Femoral Stem and Increased Risk of Thigh Bone Fracture - FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/zimmer-biomet-cpt-hip-system-femoral-stem-and-increased-risk-thigh-bone-fracture-fda-safety)	Safety Communication
10/29/2024	Important Information on Use of Unapproved Human Immunodeficiency Virus (HIV) Blood Sample Self-Collection Kits https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/important-information-use-unapproved-human-immunodeficiency-virus-hiv-blood-sample-self-collection	Safety and Availability Communication
11/15/2024	Safety and Availability Concerns with VasoView HemoPro Endoscopic Vessel Harvesting Systems - Letter to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/safety-and-availability-	Letter to Health Care Provider

Date	Communication	Type
	concerns-vasoview-hemopro-endoscopic-vessel-harvesting-systems-letter-health?utm_medium=email&utm_source=govdelivery)	
12/16/2024	Accolade Pacemaker Devices by Boston Scientific and Potential Need for Early Device Replacement - FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/accolade-pacemaker-devices-boston-scientific-and-potential-need-early-device-replacement-fda-safety)	Safety Communication

Appendix B − CDRH's 2023-2024 Device Safety-Related Communications That Provided New Information About Device Safety Recalls That Resolved the Problem

Date	Communication	Type
05/04/2023	Do Not Use Certain SD Biosensor Pilot COVID-19 At-Home Tests: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/do-not-use-certain-sd-biosensor-pilot-covid-19-home-tests-fda-safety-communication)	Safety Communication
06/09/2023	Oxygenator Devices Used for Extracorporeal Circulation - Letter to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/oxygenator-devices-used-extracorporeal-circulation-letter-health-care-providers)	Letter to Health Care Provider
11/06/2023	Recall of Certain Saline and Sterile Water Medical Products Associated with Nurse Assist: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/recall-certain-saline-and-sterile-water-medical-products-associated-nurse-assist-fda-safety)	Safety Communication
02/02/2024	Do Not Use Certain Cardinal Health Monoject Luer-Lock and Enteral Syringes - FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/do-not-use-certain-cardinal-health-monoject-luer-lock-and-enteral-syringes-fda-safety-communication)	Safety Communication
07/09/2024	Do Not Use Medtronic NIM Standard and Contact EMG Endotracheal Tubes - Letter to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/do-not-use-medtronic-nim-standard-and-contact-emg-endotracheal-tubes-letter-health-care-providers)	Letter to Health Care Provider

Date	Communication	Type
10/25/2024	Update: Do Not Use BioZorb Marker Implantable Radiographic Marker Devices: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/update-do-not-use-biozorb-marker-implantable-radiographic-marker-devices-fda-safety-communication?utm_medium=email&utm_source=govdelivery)	Safety Communication

Appendix C − CDRH's 2023-2024 Device Safety-Related Communications That Provided Updated Information—in Reference to Previous CDRH Communications—About Device Safety

Date	Communication	Type
02/07/2023	Updated: Mammography Problems at Advanced Women Imaging in Guttenberg, NJ (https://www.fda.gov/medical-devices/safety-communications/updated-mammography-problems-advanced-women-imaging-guttenberg-nj)	Safety Communication
03/07/2023	Update: Potential Risk of Exposure to Toxic Compounds When Using Hemodialysis and Peritoneal Dialysis Systems - Letter to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/update-potential-risk-exposure-toxic-compounds-when-using-hemodialysis-and-peritoneal-dialysis)	Letter to Health Care Provider
03/08/2023	UPDATE: Reports of Squamous Cell Carcinoma (SCC) in the Capsule Around Breast Implants - FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/update-reports-squamous-cell-carcinoma-scc-capsule-around-breast-implants-fda-safety-communication)	Safety Communication
05/10/2023	UPDATE: Use of Renuvion/J-Plasma Device for Certain Aesthetic Procedures: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/update-use-renuvionj-plasma-device-certain-aesthetic-procedures-fda-safety-communication)	Safety Communication
06/28/2023	UPDATE: NuVasive Specialized Orthopedics' Precice Devices - Letter to Health Care Providers	Letter to Health Care Provider

Date	Communication	Type
	(https://www.fda.gov/medical-devices/letters-health-care-providers/update-nuvasive-specialized-orthopedics-precice-devices-letter-health-care-providers)	
07/11/2023	UPDATE: Paclitaxel-Coated Devices to Treat Peripheral Arterial Disease Unlikely to Increase Risk of Mortality - Letter to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/update-paclitaxel-coated-devices-treat-peripheral-arterial-disease-unlikely-increase-risk-mortality)	Letter to Health Care Provider
08/31/2023	UPDATE: Risk of Device Failures for Getinge's Maquet/Datascope Cardiosave Intra-Aortic Balloon Pump (IABP) - Letter to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/update-risk-device-failures-getinges-maquetdatascope-cardiosave-intra-aortic-balloon-pump-iabp)	Letter to Health Care Provider
09/29/2023	Update: Recommendations for Certain O&M Halyard Surgical N95 Respirators, Surgical Masks, and Pediatric Face Masks: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/update-recommendations-certain-om-halyard-surgical-n95-respirators-surgical-masks-and-pediatric-face)	Safety Communication
10/16/2023	Evaluation of Airborne Chemicals from Neonatal Incubators - Letter to Health Care Providers (https://web.archive.org/web/20231017165454/https:/www.fda.gov/medical-devices/letters-health-care-providers/evaluation-airborne-chemicals-neonatal-incubators-letter-health-care-providers)	Letter to Health Care Provider
03/19/2024	UPDATE: Evaluating Plastic Syringes Made in China for Potential Device Failures: FDA Safety Communication	Safety Communication

Date	Communication	Type
	(https://www.fda.gov/medical-devices/safety-communications/update-evaluating-plastic-syringes-made-china-potential-device-failures-fda-safety-communication)	
05/08/2024	Safety and Quality Concerns with Getinge Cardiovascular Devices - Letter to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/safety-and-quality-concerns-getinge-cardiovascular-devices-letter-health-care-providers)	Letter to Health Care Provider
10/29/2024	Update: Use of GE HealthCare EVair and EVair 03 Compressors - Letter to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/update-use-ge-healthcare-evair-and-evair-03-compressors-letter-health-care-providers?utm_medium=email&utm_source=govdelivery)	Letter to Health Care Provider
11/08/2024	Evaluation of Airborne Chemicals from Neonatal Incubators - Letter to Health Care Providers (https://web.archive.org/web/20241224155427/https://www.fda.gov/medical-devices/letters-health-care-providers/evaluation-airborne-chemicals-neonatal-incubators-letter-health-care-providers)	Letter to Health Care Provider

This report was prepared by FDA's Office of Product Quality in the Center for Devices and Radiological Health. For information, please contact:

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This report is available on FDA's home page at https://www.fda.gov/.