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FDA

Differences Between FDA Medical Device Approval, Clearance and Registration

A Lesson for Endoscope Processing Professionals

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LEARNING OBJECTIVES

1. Learn the U.S. Food and Drug Administration's definition of "medical device" and describe Federal Code of Registration (CFR), 21 CFR
2. Discuss how to determine if a product is a medical device and understand the FDA review process for Class I, II and III medical devices
3. Understand postmarket surveillance and Medical Device Reporting (MDR)

The U.S. Food and Drug Administration (FDA) is responsible for protecting public health by regulating consumer products such as food, medications, vaccines, medical devices, radiation-emitting electronics, cosmetics, veterinary products, and tobacco. Within the FDA, the Center for Devices and Radiological Health (CDRH) is a regulatory bureau that is responsible for implementing and enforcing the laws and regulations applicable to radiation-producing electronic products and medical devices, including lasers and light devices. Medical devices include everything from tongue depressors to pacemakers. The FDA places medical devices into three classes (I, II and III), with the classification decided based on potential risk(s) of use.

Understanding the process of FDA review, clearance, approval, and reporting of patient safety issues helps endoscope processing personnel know the background of what goes into getting these devices to market. It also helps with the understanding of the validation, testing and approval processes for these devices. Reporting of patient adverse events and device malfunctions becomes an important task for healthcare facilities and therefore an understanding of the process is necessary.

Objective 1: Learn the U.S. Food and Drug Administration's definition of "medical device" and describe Federal Code of Registration (CFR), 21 CFR

A medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory, which is recognized in the official National Formulary or the U.S. Pharmacopeia,

CLASSIFICATION	DESCRIPTION	STATISTICAL INFORMATION
Class I	Low-risk devices subject to general controls	Most (but not all) Class I devices are exempt from premarket notification [510(k)]—47% of all medical devices
Class II	Moderate-risk devices subject to general and special controls	Most (but not all) Class II devices require a premarket notification [510(k)]—43% of all medical devices
Class III	High-risk devices subject to general controls and premarket approval	10% of all medical devices

or any supplement to them. A medical device is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease (in humans or other animals). A medical device is also intended to affect the structure or any function of the body of man or other animals. It does not achieve its primary intended purposes through chemical action within or on the body of humans or other animals and is not dependent upon being metabolized for the achievement of any of its primary intended purposes.[1]

A medical device accessory, on the other hand, is a finished device that is intended to support, supplement and/or augment the performance of one or more parent devices.[2] A parent device is a finished device whose performance is supported, supplemented and/or augmented by one or more accessories. If labeling, promotional materials or other evidence of intended use demonstrates that the device is intended to support, supplement and/or augment another device (whether a particular brand or a device type), that device is considered an accessory. For example, an infusion pump system may include an infusion pump and a stand. The stand supports the performance of the infusion pump by allowing the infusion pump to hold medications and liquids at an appropriate height and in convenient reach of the caregiver.

The Code of Federal Registration's (CFR's) annual edition is the written general and permanent rules published in the Federal Register by the departments and agencies of the federal government.[3]

The online CFR is a joint project authorized by the publisher, the National Archives and Records Administration's (NARA) Office of the Federal Register (OFR), and the Government Publishing Office (GPO) to provide the public with enhanced access to government information. The 50 subject matter titles contain one or more individual volumes, which are updated once each calendar year, on a staggered basis. 21 CFR is a title within the Code of Federal Regulations; Title 21 is reserved for the rules of the FDA.[3]

Objective 2: Discuss how to determine if a product is a medical device and understand the FDA review process for Class I, II and III medical devices

Medical devices are classified into Class I, II and III.[4] Regulatory control increases from Class I to Class III. The device classification regulation defines the regulatory requirements for a general device type. Most Class I devices are exempt from premarket notification 510(k); most Class II devices require premarket notification 510(k); and most Class III devices require premarket approval. A description of device classification and a link to the product classification database is available at "Classification of Medical Devices" (www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm).

If a device requires the submission of a premarket notification 510(k), you cannot commercially distribute the device until you receive a letter of substantial equivalence from FDA authorizing you to do so. A 510(k) must demonstrate that the device is substantially equivalent to one legally in commercial distribution in the U.S.: (1) before May 28, 1976; or (2) to a device that has been determined by FDA to be substantially equivalent.[5]

Premarket notification 510(k) submissions for medical devices are reviewed by the FDA's CDRH—specifically by the Office of Product Evaluation and Quality (OPEQ). There are seven device types and medical specialty offices within OPEQ. The Offices of Health Technology (OHTs) are organized according to medical device specialties. The 510(k) submissions are reviewed by OPEQ staff, including biomedical engineers, physicians, microbiologists, chemists, and other scientific professionals.[6]

A predicate device is a legally marketed device previously cleared through the 510(k) process. It is used for comparison to a new device for the purpose of determining substantial equivalence [21 CFR 807.92(a)(3)].[7]

Substantial equivalence (SE) means that the new device is as safe and effective as the predicate.[8]. A device is substantially equivalent if, in comparison to a predicate, it has the same intended use and technological characteristics as the predicate, or

it has the same intended use as the predicate; has different technological characteristics and does not raise different questions of safety and effectiveness; and the information submitted to the FDA demonstrates that the device is as safe and effective as the legally marketed device.

A claim of SE does not mean the new and predicate devices need to be identical. The FDA first establishes that the new and predicate devices have the same intended use and any differences in technological characteristics do not raise different questions of safety and effectiveness. The FDA then determines whether the device is as safe and effective as the predicate device by reviewing the scientific methods used to evaluate differences in technological characteristics and performance data. This performance data can include clinical data and non-clinical bench performance data, including engineering performance testing, sterility, electromagnetic compatibility, software validation, and biocompatibility evaluation, among other data.

Objective 3: Understand postmarket surveillance and Medical Device Reporting (MDR)

Postmarket surveillance is the process of enabling manufacturers to collect data from actual use of medical devices, analyzing the data and then using the information in the appropriate processes, such as product realization, risk management, communicating to regulatory authorities, or product improvement. The extent of a post-market surveillance process needs to be appropriate and proportionate to the medical device and its use.[9]

Each year, the FDA receives several hundred thousand medical device reports of suspected device-associated deaths, serious injuries and malfunctions.[10] Medical Device Reporting (MDR) is one of the postmarket surveillance tools the FDA uses to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products.

Mandatory reporters (manufacturers, device user facilities, and importers) are required to submit certain types of reports for adverse events and product problems to the FDA about medical devices. In addition, the FDA also encourages healthcare professionals, patients, caregivers and consumers to submit voluntary reports about serious adverse events that may be associated with a medical device, as well as use errors, product quality issues and therapeutic failures. These reports, along with data from other sources, can provide critical information that helps improve patient safety.

The MDR regulation (21 CFR Part 803) contains mandatory requirements for manufacturers, importers and device user facilities to report certain device-related adverse events and product problems to the FDA.

- Manufacturers are required to report to the FDA when they learn that any of their devices may have caused or contributed to a death or serious injury. Manufacturers must also report to the FDA when they become aware that their device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.
- Importers are required to report to the FDA and the manufacturer when they learn that one of their devices may have caused or contributed to a death or serious injury. The importer must report only to the manufacturer if their imported devices have malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.
- A "device user facility" is a hospital, ambulatory surgery center, nursing home, outpatient diagnostic facility or outpatient treatment facility that is not a physician's office. User facilities must report a suspected medical device-related death to both the FDA and the manufacturer. User facilities must report a medical device-related serious injury to the manufacturer (or to the FDA if the medical device manufacturer is unknown).

User facilities are not required to report a device malfunction but can voluntarily advise the FDA of such product problems using the MedWatch Form FDA 3500 under the FDA's Safety Information and Adverse Event Reporting Program. Healthcare professionals within a user facility should familiarize themselves with their institution's procedures for reporting adverse events to the FDA. *See "Medical Device Reporting for User Facilities," a guidance document issued by the FDA.*

In 2017, the FDA proposed that manufacturers could report certain device malfunctions in a summary on a quarterly basis, subject to certain conditions. In 2018, the FDA granted this alternative approach. Key among these principles is transparency of this information to the FDA and to the public, regardless of how the information is reported. Each summary report identifies the total number of reportable malfunctions and is available to the public in the Manufacturer and User Facility Device Experience (MAUDE) database. Importantly, submission of individuals reports of death or serious injury events continue to be required.

Under this program, manufacturers submit separate summary reports for

each unique combination of brand name, device model, and problem code(s). Each summary report identifies the total number of reportable malfunctions, and the summary reports are available to the public in MAUDE.

Although MDRs are a valuable source of information, this passive surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified or biased data. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to under-reporting of events, inaccuracies in reports, lack of verification that the device caused the reported event, and lack of information about frequency of device use. Because of this, MDRs comprise only one of the FDA's several important postmarket surveillance data sources.

Conclusion

Understanding the process of FDA review, clearance, approval and reporting of issues helps endoscope processing personnel know the background of what goes into getting these devices to market. It also helps with the understanding of the validation, testing and approval processes for these devices. Reporting of patient adverse events and device malfunctions becomes an important task for healthcare facilities and, therefore, an understanding of the process is necessary.

The next lesson will address the Safe Medical Devices Act of 1990 (SMDA; Public Law 102-629), Medical Product Safety Network (MedSun), Identifying Potential Problems Before Serious Injuries Occur, and the MAUDE database.

REFERENCES

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