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Learning Objectives

- 1) Describe the FDA's responsibilities in regulating Class II medical devices such as sterilization monitoring products.
- 2) Discuss the various ways a manufacturer can legally market a Class II medical device in the United States.
- 3) Discuss resources available to healthcare facilities when developing policies and procedures which specify the use of sterilization monitoring products.

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FDA, 510(k)s, and Standards

What they mean and how they affect you

by Bryan Becker, MS

If you have ever read "The Jungle" by Upton Sinclair, you know of the harsh conditions of an early 20th century meat processing plant. Accounts of unsanitary conditions in meat-packing plants, the use of poisonous preservatives and dyes in foods, and cure-all claims for medicines were major problems during this time. President Theodore Roosevelt and Congress enacted the Food and Drugs Act in 1906 to address some of these concerns. This time in US history was the birthplace of modern food, drug, cosmetic, and medical device regulations. Today, the Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, efficacy, and security of drugs, biological products, medical devices, the nation's food supply, cosmetics, and products that emit radiation.

The US Food and Drug Administration regulation of medical devices and their related standards can be confusing to users of these products. Terms such as "clearance" and 510(k) mean very little to most people unless they work with medical devices. The purpose of this self-study article is to shed some light on the FDA and their regulation of sterilization monitoring products. Without a basic understanding, this topic can easily become confusing. The FDA has categorized medical devices into three categories based on their risk to users and patients. These categories are Class I (lower risk items such as bandages), Class II (higher risk items such as surgical drapes and gowns and chemical and biological indicators), and Class III (high risk or life supporting devices such as pacemakers). It should be noted that this article is specific to FDA-Class II devices, notably sterilization process indicators.

What does the FDA do?

The Food, Drug, and Cosmetics Act (often called the FD&C Act or simply "The Act") of 1938 is the groundwork for the modern regulation of products such as medical de-

vices. This act defines medical devices, drugs, and cosmetics and gives the federal government the responsibility of overseeing their safety. The FDA regulates the manufacturers, sellers, and distributors of medical devices. They review product submissions from manufacturers to assure the products that are sold are safe and effective when the product's instructions are followed. The FDA does not regulate hospitals, physicians, or other healthcare practitioners. For instance, the FDA regulates chemical and biological indicators and the companies who make and sell them but not the healthcare professionals who use them. The specific use and frequency of use of these medical devices are determined by the healthcare facility and healthcare professional. How you choose to use them should be based on your facility's policies and procedures. These policies and procedures, in turn, should be based upon standards, guidelines, and recommended practices, such as those published by the Association for the Advancement of Medical Instrumentation (AAMI), the Association of periOperative Registered Nurses (AORN), the Centers for Disease Control and Prevention (CDC), and local laws and regulations, if applicable.

Whether a vendor satisfies the proper regulatory requirements to sell a medical device should be one factor considered when evaluating a new device for use in your facility. While this sounds straightforward, there are a variety of ways a FDA-Class II medical device can be legally sold in the US market place.

The pre-amendment medical device

The FDA Medical Device Amendments of 1976 were an important development. These amendments introduced the 510(k) (which we will discuss later). FDA-Class II medical devices, like chemical and biological indicators, sold before the Medical Device Amendments were introduced are

considered “pre-amendment.” FDA-Class II devices introduced to the US market after the Medical Device Amendments (i.e. after May 28, 1976) require a 510(k) before they can be sold in the US. It should be noted that pre-amendment devices are required to meet other FDA requirements for design changes, manufacturing, and quality systems but can still be legally sold without a 510(k) clearance.

This can be a point of confusion in the marketplace. If you simply ask for an FDA 510(k) letter and the company cannot provide one, it most likely means the product is pre-amendment. As stated above, pre-amendment products are required to follow all current FDA requirements but if they have not changed significantly since they were first put on the market they can continue to be legally sold without a 510(k).

The 510(k) Medical Device

510(k)s are also known as Premarket Notifications (PMN). The name 510(k) is from section 510, item “k” of the Medical Device Amendments.

The FDA defines a 510(k) as: “A submission made to FDA to demonstrate that a device is at least as safe and effective as another legally marketed device.”

This brings us to the FDA terms of “legally marketed,” “substantially equivalent,” and “clearance.” Products that require 510(k) submissions must be substantially equivalent to a device already on the market. That means the testing data on the new product must not raise new questions about the device’s safety or effectiveness when compared to another device on the market.

A good analogy to this process is buying a new car. If you drive a mid-size family sedan and you are looking to buy another mid-size family sedan, then you may take some test drives and kick some tires but for all practical purposes most of these types of cars are pretty similar. You might call some of them substantially equivalent. Now, if you are tired of the mid-sized sedan and want to buy a convertible sports car then that is a little different. They are both cars but may not be substantially equivalent. You may have more questions about the safety and performance of the sports car and you may require more data to make a decision.

This example is similar to how the 510(k) review process works. If a new product (new sedan) performs and is as safe as a currently marketed product (your current sedan), then they can be considered substantially equivalent and the new product can be legally marketed (you could buy it). If the new product (sports car) raises questions about safety and efficacy when compared to a currently marketed product (your current sedan), then more data would most likely be needed to show whether it is substantially equivalent or not (you may or may not buy it based on the information you receive).

If the device is as safe and effective as a device on the market and substantial equivalence is determined, then the 510(k) is “cleared.” The FDA is very adamant that 510(k) clearance does not mean a device is ‘approved’. Unlike new drugs, which are approved for sale by the FDA, Class II medical devices can be legally marketed after being cleared. Legally marketed means the device has either been cleared via a 510(k) or was already on the market prior to the Medical Device Amendments (pre-amendment).

Types of 510(k)’s

There are several different types of 510(k)s:

- o The traditional 510(k) is mainly for new products.
- o The “Special” 510(k) is for significant changes to products that already have a traditional 510(k) clearance.
- o Finally, there are “Abbreviated” 510(k)’s based on FDA recognized standards.

An abbreviated 510(k) is based on a consensus standard developed by a standards body – such as AAMI or the International Organization for Standardization (ISO) – and reviewed and recognized by the FDA. The FDA Modernization Act of 1997 allows the FDA to recognize standards for Abbreviated 510(k)s. Once the FDA recognizes all or part of a standard, a manufacturer can submit an Abbreviated 510(k) that declares that the device is in conformance with the recognized standard. What is the advantage? One of the goals of the Modernization Act was to speed up submission review times at the FDA. By declaring conformity to a recognized standard, the FDA does not need to review certain types of efficacy data during the 510(k) review process. The premise is that less data means

less time in review and products can be brought to market faster.

Other ways to legally market a medical device

The type of 510(k) under which a device is cleared is of little consequence to the user of the device. The main point is that a product can be legally sold with any of the types of 510(k) clearances, as a pre-amendment device, or in a variety of other ways. Here are some of those other ways:

- o Company ABC puts their labeling on company XYZ’s product (private label) and sells the product with ABC’s labeling but under company XYZ’s 510(k) clearance.
- o Company ABC buys company XYZ and sells products under XYZ’s 510(k) clearances.
- o Company ABC gets 510(k) clearance for product D. They later change only the name of the product to product E and do not file for a new 510(k).

Because there are many different ways to legally market a product, the main message here is that if you ask for regulatory compliance information when evaluating a new product, realize that the company’s explanation of its compliance may be more complicated than a simple FDA 510(k) clearance letter.

FDA standards recognition

FDA standards recognition is mainly for the purpose of 510(k) submissions and is not an endorsement of a standard. The FDA does not develop standards (but may be active in standards committees) nor do they require products to follow standards. Conformance to FDA recognized standards is strictly voluntary. When recognized by the FDA, AAMI and ISO standards are referenced in Abbreviated 510(k) submissions to the FDA. Since standards recognition is voluntary, a company can choose to submit a product in an Abbreviated 510(k) to the FDA or to submit the same product in a traditional 510(k). The selected submission path depends upon a number of factors, including regulatory strategy.

In the field of sterilization assurance monitoring products, a major point of confusion about FDA requirements and ISO standards is the lack of harmony in the definitions. For instance, ANSI/AAMI/ISO 11140-1:2005, *Sterilization of health care prod-*

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ucts - Chemical indicators - Part 1: General requirements, splits these products into six classes. On the other hand, the FDA describes only three categories for chemical indicators (CIs) in their guidance document for CI 510(k) submissions:

- o Process indicators (distinguish between processed and unprocessed goods)
- o Chemical integrators (an indicator that reacts to all critical sterilization parameters over a specified range of sterilization cycles)
- o Air removal indicators (such as Bowie-Dick test packs).

There is very little alignment between the two sets of definitions. For instance, the FDA can clear a 510(k) for an FDA-defined integrator that does not meet any ISO class per the 2005 standard. The main point to understand is that FDA clearance as one of the three types of chemical indicators is required to sell a new chemical indicator in the US but conformance to one of the six types of chemical indicators described in ISO 11140-1:2005 is not required to obtain clearance.

Evaluating FDA regulatory compliance

Let's say you are comparing three different chemical indicators. Let's pretend that they are record cards with a process indicator on the card and your job is to determine if they are compliant with FDA regulations. The three products are:

- o Brand A: Does not have a 510(k) clearance letter because it is pre-amendment (it has been on the market since 1970) but claims to meet the ISO 11140:2005 Class 1 standard.
- o Brand B: Has a 510(k) from 1982 and does not claim to meet any standard. When you ask for the 510(k) clearance, the company gives you the FDA clearance letter with a different company's name on it. It turns out that they purchased the company in 1992 and have not filed a 510(k) on this product themselves.
- o Brand C: Has an Abbreviated 510(k) from this year and meets the ISO 11140:2005 Class 1 standard.

You begin your decision making process with basic FDA compliance. Is Brand A worse because it is pre-amendment and doesn't have a 510(k)? No, it may actually be a wise choice because it has been on the market for a long time — bad products usually don't stay on the market for that long — and it meets the newest standard. Brand B has also been on the market for a while

but lacks compliance to the latest standard and is cleared under another company's name. Brand C is new AND meets the newest standard. So which is the most FDA compliant product? They all are! All of these products are "legally marketed" according to FDA regulations.

When evaluating a product for FDA regulatory compliance it can be confusing. There are many ways to meet the FDA requirements to legally market a product. Some of those ways have been addressed in this article. If you have any questions about how a company legally markets a product you should ask the company for further explanation or contact the FDA's Center for Devices and Radiological Health via the Consumer Information website (<http://www.fda.gov/cdrh/consumer/geninfo.html>) or by calling (888) INFO-FDA.

What about ANSI/AAMI/ISO 11140-1:2005 Class 5 and Class 6 chemical indicators?

There has been some confusion about Class 5 and Class 6 chemical indicator (CI) products. The AAMI ST 79 standard has guidelines for the use of Class 5 CI products but not for the use of Class 6 CIs. The FDA recognizes Class 6 CIs but not Class 5 CIs. What does this mean?

Recall that the FDA accepts conformance to recognized consensus standards for Abbreviated 510(k)s. FDA standards recognition means more to a manufacturer's Regulatory Affairs department than to the user. The current FDA recognition of ISO 11140-1:2005 is for Class 1, 2, and 6 (with extra testing required for Class 6 products). This simply means a company can submit an Abbreviated 510(k) for a Class 1, 2, or 6 CI but not a Class 3, 4, or 5 CI. Beyond that, FDA recognition of only selected parts of the ISO 11140-1:2005 standard means little to the healthcare professional. The FDA clearance of Class 6 products means that the products are safe and effective when they are used per the product's instructions. The FDA does not clear sterilization monitoring products for specific uses (such as releasing implant loads) because establishing the frequency and uses of sterilization monitoring products is the responsibility of the healthcare facility.

AAMI and AORN recommended practices are the best source documents available to assist healthcare professionals in the development of a facility's sterilization policies and procedures.

ANSI/AAMI ST79:2006 provides guidance on the use of Class 5 integrating indicators but not on the use of Class 6 chemical indicators. AAMI Working Group 40, the committee responsible for the maintenance of ST 79, is still reviewing the proper way to include Class 6 in the standard. ANSI/AAMI ST79:2008, will include the ISO definition for the Class 6 emulating indicators and the following note:

"NOTE-This edition of ANSI/AAMI ST79 does not cover the use and application of Class 6 emulating indicators. Refer to the manufacturer's written instructions for use."

AORN Recommended Practices do not yet discuss the use of Class 6 emulating indicators.

When questioned by an auditor or in a court of law, one of the best defenses a healthcare professional can have is to have followed a national or international standard or recommended practice when developing their facility's policies and procedures. When assessing whether or not to deviate from a standard, it would be wise to assure that it is done based on sound scientific data and that the proper people (facility product evaluation committee or infection control committee, Infection Preventionist, risk management, etc.) are involved in the decision. The FDA reviews products for safety and efficacy, but user standards should guide your facility's policies and procedures which prescribe how those products are used. If using a product requires deviation from a standard, then proper data should be available to support that use. A decision to deviate from a national standard, guideline, or recommended practice (or even a specific product's instructions for use) is within your authority as a healthcare professional but should be approached with caution. Such a decision should only be made after asking questions, gathering data to support the decision, understanding any risks, and obtaining consent from the necessary facility stakeholders.

So what does all this mean to you?

It is important to understand the role of FDA clearance in the sterilization monitoring products you use. Products can be legally sold in a variety of ways and a basic understanding of the way these products meet regulatory requirements is required to make an informed decision. FDA regulatory compliance is very important but is

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only the starting point for reviewing a product's suitability for use in a healthcare facility. The FDA regulates the products and the companies that make and sell them. It is up to the healthcare professional to determine how to incorporate them into their practice. Standards and recommended practices provide guidance on the use and frequency of use of sterilization monitoring products. This guidance is developed by committees, comprised of users, industry and regulatory agency representatives and independent experts, who rely on their experience and published scientific information for their input. Some standards are used to help the FDA clear products for marketing but companies are not required to make products that follow a FDA recognized standard. Electing to develop policies and procedures that deviate from user standards or recommended practices should be approached with caution and include the evaluation of scientific data and involvement of all interested parties. **HPN**

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Circle the one correct answer:

- The FDA regulates manufacturers of Class II medical devices.
A. True
B. False
- The FDA regulates the use of Class II medical devices in healthcare facilities.
A. True
B. False
- Medical devices introduced before 1976 cannot be legally marketed.
A. True
B. False
- Medical devices introduced before 1976 are described as "pre-amendment" and therefore may not have a 510(k).
A. True
B. False
- If a manufacturer makes significant changes to a medical device which has a traditional 510(k), they must file a special 510(k) to obtain clearance to market the modified product.
A. True
B. False
- A manufacturer may choose to file an abbreviated 510(k) submission by declaring a product conforms to an FDA recognized consensus standard.
A. True
B. False
- The FDA's chemical indicator definitions align perfectly with the CI classifications specified in ANSI/AAMI/ISO 11140-1:2005, *Sterilization of health care products - Chemical indicators - Part 1: General requirements*.
A. True
B. False
- To obtain FDA clearance, a chemical indicator manufacturer must claim their device conforms to one of the ISO 11140-1:2005 CI classifications recognized by the FDA.
A. True
B. False
- It is the responsibility of the healthcare facility to determine the use and frequency of use of sterilization monitoring products.
A. True
B. False
- Prudent sterile processing managers base their sterilization assurance policies and procedures on standards and recommended practices published by national standards associations or professional societies such as AAMI and AORN.
A. True
B. False

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