



Global Trends and Customs:

What Do Dental Floss, Bedpans, and Pacemakers Have in Common?

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Who knew dental floss was a medical device regulated by the U.S. Food and Drug Administration (FDA)? What about contact lenses, tongue depressors, or bedpans? How about pacemakers? You guessed it, they all are!

One might naturally think of a product like a defibrillator as a medical device, but in our business, we find many companies unsure if its products are, in fact, medical devices.

The following is the first of a two part series which you may use as a helpful guide to get you through the medical device maze. First is a description of what medical devices are, and helpful hints so that you may identify if your product is regulated as a medical device. Second is a brief overview of FDA's regulation of medical devices. The second part of the series will discuss the classes of medical devices, and the FDA registration process.

What is a Medical Device?

The technical definition of a medical device, found in section 201(h) of the Federal Food Drug & Cosmetic Act (FD&C Act) 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:

1) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

If you are asking how you would know if your product fits that definition, keep reading. You could check the official National Formulary, or the United States Pharmacopoeia. If you do not have either book handy, the next step is to think about what your product is used for. For example, if you wanted to know whether or not contact lenses were considered a medical device by the FDA, you could first consider what contacts are used for. Dictionary.com defines **contact lenses** as "plastic disks that are held in place over the cornea by surface tension and correct vision defects inconspicuously"¹. Utilizing this definition, contact lenses can be used to affect the function of a persons eye sight, or used therapeutically to assist in the treatment of an eye disease. We would then look back at the technical definition of a medical device, and realize contact lenses can fit in either (2) or (3) above, and would therefore fit into FDA's definition of a medical device.

There is another way to go about this. This way is not foolproof, but it is not a bad place to start. The FDA has a “Classification Database,”² where you may search to see how medical devices are classified by the FDA. You can also utilize this website to work backwards to see if your product is regulated by the FDA as a medical device. For example, if you were to type “contact lens” in the search box, we would see “22 records meeting your search criteria returned - contact lens”. From the search result, it is a safe assumption that contact lenses are treated as a medical device by the FDA. The database contains other technical information, which will be discussed in Part 2 of this series, including the product code and device class.

Otherwise, consider consulting an experienced import compliance attorney already familiar with the process for a legal opinion.

FDA’s regulation of Medical Devices

FDA’s Center for Devices and Radiological Health (CDRH) is responsible for regulating firms who manufacture, repackage, relabel, and/or import medical

devices sold in the United States. FDA regulates medical devices to assure the products safety and effectiveness. FDA’s legal authority to regulate medical devices stems from the FD&C Act. The FD&C Act contains requirements, which specify what level of control FDA will have over medical devices. The FDA implements regulations to implement the provisions of the FD&C Act. These regulations are initially published in the Federal Register (FR) for public comment. FDA reviews the public comments, and then issues a final regulation. The FR contains both the proposed and final regulations. Final regulations are subsequently placed or codified into the Code of Federal Regulations (CFR) on an annual basis. Most of FDA’s medical device regulations may be found in Title 21 CFR Parts 800-1299.

Conclusion

Now you can determine whether or not your product is in fact a medical device, and have an understanding of FDA’s regulation of medical devices. Stay tuned to learn more about FDA’s classes of medical devices, and the FDA registration process. ■

¹ <http://dictionary.reference.com/browse/contact%20lens>

² <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/PCDSimpleSearch.cfm>

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