Accessories

The Context
The Food, Drug, and Cosmetics Act, FD&CA, includes a definition of a medical device. Section 201(h) says the term "device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is …

As a result, an accessory is a medical device and consequently regulated by FDA. This includes, pre-market submissions, a quality management system that satisfied QSR, Unique Device Identification, Medical Device Reports, *etc*.

The Warning Letter
On December 11, 2015, FDA sent a Warning Letter to Elite Massagers, LLC, a manufacturer of the Elite Massager Mono, Elite Massager Multi, Elite Massager Multi-Pro, Elite Massage Shoes, Elite Massage Belt, Elite Heat Pocket pack, Elite Heat Lower Back pack, Elite Heat Shoulder pack, Elite Heat Combo pack, and Elite Heat Back strap.

Elite Massagers, LLC is in Richardson, Texas. The Warning Letter was the result of an FDA inspection.

The Issue Cited
The Warning Letter cites a failure to obtain pre-market approval or clearance before marketing accessories.

The citation says, "Your firm also markets accessories, specifically, the Elite Massage Belt and Elite Massage Shoes, which are intended to be used in conjunction with your Elite Massagers. A review of our records reveals that you have not obtained marketing approval or clearance before you began offering these accessories for sale, which is a violation of the law. In addition, your Elite Massage Belt and Elite Massage Shoes are not covered by K121719."

The Warning Letter further explains, "The Elite Massage Shoes and Elite Massage Belt appear to fall under product code GXY, under regulation 21 CFR §882.1320 Cutaneous electrode. A cutaneous electrode is an electrode that is applied directly to a patient's skin either to record physiological signals (*e.g.*, the electroencephalogram) or to apply electrical stimulation."

The Requirement
The requirement is not so much a regulation, but to determine if an article is an accessory. If yes, then the manufacturer needs to classify it and submit the appropriate pre-market documentation.

To assist, FDA-CDRH, on January 30, 2017, issued a corrected final guidance entitled *Medical Device Accessories – Describing Accessories and Classification Pathway for New Accessory Types*. It explains how to determine if an article is an accessory.

An accessory must have a parent device, so identify the parent device including the classification regulation, the product code, risk class, and the pre-market submission type.

Use the information about the accessory to determine its relationship to the parent device. The article is an accessory if it supports, supplements, or augments the safety or performance of the parent device.

Determine the risk of the accessory; it may not be the risk class of the parent device.

Determine if the accessory is already classified.

Make the pre-market submission for the accessory. After FDA clears or approves the accessory, market it.

Recommendations

Review your product catalog. For every item in the catalog, record:

- The catalog number
- The Device Identification (from UDI)
- The clearance or approval number from FDA

If you have a catalog item that goes with a medical device, it may be an accessory.

Follow the methods in the guidance document cited above, document your decisions, and take appropriate action. In particular, during an FDA Inspection, your documented rationale will be very valuable if the Investigator believes an article is an accessory and you determined it is not.