FD&CA Amended for Accessories

The recently enacted FDARA, Public Law 115-52, (https://www.congress.gov/bill/115th-congress/house-bill/2430#) includes an amendment that covers medical device accessories. This law repeals and replaces the section on accessories in the 21st Century Cures Act.

The law amends section 513(f) of the FD&CA, 21 USC 360c, by adding a new paragraph. The information below summarizes the amendment.

The Secretary classifies an accessory by written order based on the risk when used as intended and the regulatory controls necessary. The accessory's classification doesn't depend on the classification of any device it is used with.

Any accessory classification, by regulation or written order, that is distinct from another device and issued before December 13, 2016 continues to apply.

For a device intended for use with an accessory where the accessory is included in a PMA or 510(k) and the accessory is not separately classified, the person filing the application for the device may:

- Include a written request for classification of the device
- Include information to help evaluate the appropriate for the accessory
- If the request is for Class II, include a draft of any special controls

For an accessory covered by a PMA or a 510(k) for another device one year after enactment of FDARA and at least every five years the Secretary publishes a list of these device suitable for Class I. The list has a 60 day comment period. Within 180 days of the close of the comments, the Secretary publishes the list of accessories reclassified.

A manufacturer or importer may submit a written request to reclassify an accessory. If the request is for Class II, include a draft of any special controls. The Secretary responds within 85 calendar days by either classifying the accessory or denying the request.