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Client Alert

FDA and Life Sciences

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FDA Issued Draft Objective Performance Criteria For Five Device Types

Implications for 510(k) Submissions

On September 20, 2019, FDA issued four separate draft guidance documents for industry and FDA administration staff that provide extensive objective performance criteria (OPC) for five types of devices in support of the Safety and Performance Pathway.[1] With this step, FDA further developed the implementation of the Safety and Performance Pathway that the Agency described in its February 2019 Final Guidance.[2] The draft guidance documents address the following devices:

- Balloon-Retention Foley Catheters (procode EZL, 21 CFR 876.5130)
- Neurological-Recording Cutaneous Electrodes (procode GXY, 21 CFR 882.1320)
- Orthopedic Non-Spinal Metallic Bone Screws (procode HWC, 21 CFR 888.3040) and Washers (procode HTN, 21 CFR 888.3030[3])
- Anterior Cervical or Anterior/Lateral Thoracolumbar Titanium Spinal Plating Systems (procode KWQ, 21 CFR 888.3060)

FDA requests separate comments on each of the draft guidance documents with proposed OPC by December 19, 2019. Directions on how comments may be submitted are available here.

CONSIDERATIONS FOR 510(K) APPLICANTS

As provided by the Safety and Performance Pathway, 510(k) applicants for the types of devices with FDA-defined OPC may choose to submit their 510(k)s under this pathway and support the submission by showing only that the subject device meets the defined OPC. Under this pathway, there is no need for comparative testing of the subject device against its predicate device(s). If all of the OPC cannot be met, the 510(k) applicant should instead explore the Traditional, Abbreviated or Special 510(k) submission pathway.

The potential gains for manufacturers interested in marketing a type of 510(k) device that has FDA-defined OPC include clarity on the thresholds for 510(k) clearance as well as a less burdensome approach. In addition, manufacturers may incur savings from not having to acquire the predicate devices for comparative testing and avoiding development of the testing procedure for each comparative test.

On the other hand, for companies that already have marketed 510(k) devices, the existence of FDA-defined OPC may lead to market pressure for the device to, at a minimum, meet the FDA-defined OPC. Note that FDA clearly identifies that the Agency plans to have ongoing review of OPC and update them in accordance with its good guidance practices.

Further, while FDA based the OPC in its first two draft OPC guidances on recognized industry consensus standards, the Agency derived OPC from cleared 510(k) submissions for the devices described in the other two draft guidances. For these latter devices, FDA has proposed OPC even though recognized industry standards have not yet been established. The implication is that, even in the absence of Agency-recognized consensus standards, FDA may establish OPC for particular types of devices based on cleared 510(k)s.

The OPC described in the draft guidances likely reflect FDA's present thinking; however, FDA has noted that the draft guidances "are not final nor are they in effect at this time."[4] Accordingly, pending their finalization, any party that may be contemplating submission of a 510(k) for a device covered by one of the draft guidances should confer with FDA or seek further advice prior to developing a 510(k) based on the OPC described.

King & Spalding will continue to monitor this important developing area and provide updates accordingly. We are happy to assist you in preparing comments on any of the draft guidances.

ABOUT KING & SPALDING

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This alert provides a general summary of recent legal developments. It is not intended to be and should not be relied upon as legal advice. In some jurisdictions, this may be considered "Attorney Advertising."

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[1] "Conventional Foley Catheters – Performance Criteria for Safety and Performance Based Pathway." Accessible at https://www.fda.gov/media/130865/download ; "Cutaneous Electrodes for Recording Purposes – Performance Criteria for Safety and Performance Based Pathway." Accessible at https://www.fda.gov/media/130864/download ; "Orthopedic Non-Spinal Bone Screws and Washers – Performance Criteria for Safety Performance Based Pathway." Accessible at https://www.fda.gov/media/130866/download ; "Spinal Plating Systems – Performance Criteria for Safety and Performance Based Pathway." Accessible at https://www.fda.gov/media/130867/download

[2] Final guidance on the Safety and Performance Pathway is available at, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway. It was also updated with additional references in the footnotes and reissued on the same date as the four OPC draft guidance documents.

[3] We noted that procode HTN (washer, bolt nut) is associated with 21 CFR 888.3030 and have added this regulation accordingly.

[4] FDA, Safety and Performance Based Pathway Device-Specific Guidance; Draft Guidances for Industry and Food and Drug Administration Staff; Availability, 84 Fed. Reg. 49528 (Sept. 20, 2019); available at https://www.govinfo.gov/content/pkg/FR-2019-09-20/pdf/2019-20370.pdf.