4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2019-D-1647, FDA-2019-D-1649, FDA-2019-D-1651, and FDA-2019-D-1652]

Safety and Performance Based Pathway Device-Specific Guidance; Draft Guidances for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of several device-specific draft guidance documents for the Safety and Performance Based Pathway--specifically, "Spinal Plating Systems--Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff"; "Cutaneous Electrode for Recording Purposes--Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff"; "Conventional Foley Catheters--Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff"; and "Orthopedic Non-Spinal Metallic Bone Screws and Washers--Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff." The device-specific draft guidances identified in this notice were developed in accordance with the finalized guidance entitled "Safety and Performance Based Pathway." These draft guidances are not final nor are they in effect at this time.

DATES: Submit either electronic or written comments on the draft guidances by **[INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** to ensure that the Agency considers your comment on these draft guidance documents before it begins work on the final version of the guidance documents.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include Docket No. FDA-2019-D-1647 for "Spinal Plating Systems--Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff"; Docket No. FDA-2019-D-1649 for "Cutaneous Electrode for Recording Purposes--Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff"; Docket No. FDA-2019-D-1651 for "Conventional Foley Catheters--Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff"; and Docket No. FDA-2019-D-1652 for "Orthopedic Non-Spinal Metallic Bone Screws and Washers--Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff." Received comments will be placed in the dockets and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT

CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidances are available for download from the internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidances. Submit written requests for a single hard copy of the draft guidances entitled "Spinal Plating Systems--Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff," "Cutaneous Electrode for

Recording Purposes--Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff," "Conventional Foley Catheters--Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff," or "Orthopedic Non-Spinal Metallic Bone Screws and Washers--Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff" to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Jason Ryans, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1613, Silver Spring, MD 20993-0002, 301-796-4908.

SUPPLEMENTARY INFORMATION:

I. Background

These device-specific draft guidances provide performance criteria for premarket notification (510k) submissions to support the optional Safety and Performance Based Pathway, as described in the guidance entitled "Safety and Performance Based Pathway."[1] As described in that guidance, substantial equivalence is rooted in comparisons between new devices and predicate devices. However, the Federal Food, Drug, and Cosmetic Act does not preclude FDA from using performance criteria to facilitate this comparison. If a legally marketed device performs at certain levels relevant to its safety and effectiveness, and a new device meets those levels of performance for the same characteristics, FDA could find the new device as safe and

[1] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway.

effective as the legally marketed device. Instead of reviewing data from direct comparison testing between the two devices, FDA could support a finding of substantial equivalence with data demonstrating the new device meets the level of performance of an appropriate predicate device(s). Under this optional Safety and Performance Based Pathway, a submitter could satisfy the requirement to compare its device with a legally marketed device by, among other things, independently demonstrating that the device's performance meets performance criteria as established in the above-listed guidances, when finalized, rather than using direct predicate comparison testing for some of the performance characteristics.

II. Significance of Guidance

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on performance criteria for the "Safety and Performance Based Pathway for Spinal Plating Systems," "Cutaneous Electrode for Recording Purposes," "Conventional Foley Catheters," and "Orthopedic Non-Spinal Metallic Bone Screws and Washers." They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. These guidances are not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidances may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. These draft guidances are also available at https://www.regulations.gov. Persons unable

to download an electronic copy of either "Spinal Plating Systems--Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff (document number 19008)," "Cutaneous Electrode for Recording Purposes--Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff (document number 19014)," "Conventional Foley Catheters--Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff (document number 19010)," or "Orthopedic Non-Spinal Metallic Bone Screws and Washers--Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff (document number 19009)" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the documents. Please use the document number and complete title to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

These draft guidance documents refer to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information have been approved by OMB as listed in the following table:

21 CFR Part or Guidance	Topic	OMB Control No.
807, subpart E	Premarket Notification	0910-0120
"Requests for Feedback on Medical Device Submissions: The Q-Submission Program and Meetings with Food and Drug Administration Staff"	Q-Submissions	0910-0756

Dated: September 16, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-20370 Filed: 9/19/2019 8:45 am; Publication Date: 9/20/2019]