TABLE 2—GUIDANCES AND COLLECTIONS

21 CFR part or guidance	Topic	OMB Control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo classification process	0910–0844
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-submissions	0910–0756
803	Medical Devices; Medical Device Reporting; Manufacturer reporting, importer reporting, user facility reporting, distributor reporting.	0910–0437
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
807, subparts A through D	Electronic Submission of Medical Device Registration and Listing	0910–0625
806	Corrections and Removals	0910–0359
830 and 801.20	Unique Device Identification	0910–0720
800, 801, and 809	Medical Device Labeling	0910–0485
''Emergency Use Authorization of Medical Products and Related Authorities''.	Emergency Use Authorization	0910–0595

IV. Other Issues for Consideration

As discussed in the draft guidance, FDA understands that it will take time for device manufacturers, healthcare facilities, healthcare providers, patients, consumers, and FDA to adjust from policies adopted and operations implemented during the declared PHE to normal operations. FDA encourages all stakeholders to comment on the following topics:

1. Whether the 180-day transition period before FDA withdraws the guidances identified in List 1 would sufficiently allow for an appropriate transition period that avoids exacerbating product shortages and supply chain disruptions.

2. Suggestions to add or remove guidances documents to or from List 1 of the draft guidance.

3. FDA's proposal to extend the effectiveness of the guidances in List 1 of the draft guidance either for 180 days or for at least 225 days, if the PHE declaration under section 319 of the Public Health Service Act expires before the finalization of this guidance.

Dated: December 20, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–27892 Filed 12–22–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–5606]

Arthroscopy Pump Tubing Sets Intended for Multiple Patient Use—Premarket Notification (510(k)) Submissions; Guidance 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 a final guidance entitled ''Arthroscopy Pump Tubing Sets Intended for Multiple Patient Use—Premarket Notification (510(k)) Submissions.'' FDA has developed this guidance document to assist in the preparation of premarket notification submissions (510(k)) for arthroscopy pump tubing sets intended for multiple patient use. This guidance outlines the device design considerations, risk mitigation strategies, and testing recommendations for arthroscopy pump tubing sets intended for multiple patient use. This guidance also clarifies the terminology used to describe arthroscopy pump tubing sets intended for multiple patient use.

DATES: The announcement of the guidance is published in the **Federal Register** on December 23, 2021.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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 the Docket No. FDA–2019–D–5606 for ''Arthroscopy Pump Tubing Sets Intended for Multiple Patient Use—Premarket Notification (510(k)) Submissions.'' Received comments will be placed in the docket 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, 240–402–7500.

• 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.govinfo.gov/content/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, 240–402–7500.

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

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Arthroscopy Pump Tubing Sets Intended for Multiple Patient Use—Premarket Notification (510(k)) Submissions'' to the Office of Policy, 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: Laurence Coyne, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4512, Silver Spring, MD 20993–0002, 301–796–6450.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and FDA staff entitled ''Arthroscopy Pump Tubing Sets Intended for Multiple Patient Use—Premarket Notification (510(k)) Submissions.'' FDA has developed this guidance document to assist in the preparation of premarket notification submissions (510(k)) for arthroscopy pump tubing sets intended for multiple patient use. These devices are designed to deliver irrigation fluid to the surgical site, such as knee, shoulder, hip, elbow, ankle, and wrist joint cavities, during arthroscopic procedures. In arthroscopic procedures, clinicians often use a single source of irrigation fluid for multiple patients without replacing the source of irrigation fluid or replacing/reprocessing the irrigation tubing system between patients. This practice may increase the risk of cross-contamination between patients and subsequent iatrogenic infection because the irrigation system can become contaminated with patient fluids that travel back through the irrigation tubing (''backflow''). FDA has received reports of backflow of patient fluids which raises the question of potential for disease transmission when using irrigation and tubing systems in such a manner on multiple patients.

This guidance is intended to provide recommendations for information to include in premarket notifications (510(k)s) for arthroscopy pump tubing sets intended for multiple patient use. This guidance outlines device design considerations, risk mitigation strategies, and testing recommendations for these devices, and clarifies the terminology used to describe arthroscopy pump tubing sets intended for multiple patient use.

A notice of availability of the draft guidance appeared in the **Federal Register** of January 28, 2020 (85 FR 4997). FDA considered a comment received and revised the guidance to add a reference to an applicable FDA guidance, ''Applying Human Factors and Usability Engineering to Medical Devices.''

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Arthroscopy Pump Tubing Sets Intended for Multiple Patient Use—Premarket Notification (510(k)) Submissions.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance 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/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products*. This guidance document is also available at *https://www.regulations.gov* and at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*. Persons unable to download an electronic copy of ''Arthroscopy Pump Tubing Sets Intended for Multiple Patient Use—Premarket Notification (510(k)) Submissions'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500066 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR part	Topic	OMB Control No.
807, subpart E	Premarket notification	0910–0120
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910–0073

Dated: December 17, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–27823 Filed 12–22–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–1149]

Transition Plan for Medical Devices Issued Emergency Use Authorizations During the Coronavirus Disease 2019 Public Health Emergency; Draft Guidance for Industry and Food and Drug Administration Staff; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.'' FDA recognizes that it will take time for device manufacturers, healthcare facilities, healthcare providers, patients, consumers, and FDA to adjust from policies adopted and operations implemented during the declared public health emergency (PHE) to normal operations. To provide a clear policy for all stakeholders and FDA staff, the Agency is issuing this guidance to describe FDA's general recommendations for this transition process with respect to devices issued EUAs during the COVID–19 PHE, including recommendations regarding submitting a marketing submission, as applicable, and taking other actions with respect to these devices. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by March 23, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit either electronic or written comments on the proposed collection of information in the draft guidance by February 22, 2022.

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 the Docket No. FDA–2021–D–1149 for ''Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.'' Received comments will be placed in the docket 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

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

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for