



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-4792]

Regulatory Considerations for Microneedling Products; 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 “Regulatory Considerations for Microneedling Products.” This guidance is being issued to assist industry in understanding when a microneedling product is a device as defined in the Federal Food, Drug, and Cosmetic Act (FD&C Act). This document also provides information on the regulatory pathway to market for microneedling devices for aesthetic use.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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-2017-D-4792 for “Regulatory Considerations for Microneedling Products.” 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 “Regulatory Considerations for Microneedling Products” to the Office of the Center Director, 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: Kimberly Ferlin, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4522, Silver Spring, MD 20993-0002, 240-402-1834.

SUPPLEMENTARY INFORMATION:

I. Background

“Microneedling products” is a generic term that encompasses instruments with common technological features that include an array of needles, “micro-protrusion” tips, or pins, which can be blunt or sharp, and of varying lengths. This document discusses when a microneedling product is a device as defined under section 201(h) of the FD&C Act (21 U.S.C. 321(h)), and is, therefore, subject to the device requirements under the FD&C Act and its implementing regulations.¹ This guidance also provides clarity on the regulatory pathway to market for microneedling devices for aesthetic use, resulting in more transparency and predictability to firms and stakeholders, which may translate into more efficient device development and patient access to such devices. The scope of this guidance document does not include microneedling combination products, acupuncture needles, hypodermic needles or other needles for injection, tattoo machine needles, needle probes that emit any type of energy (e.g., radio-frequency needles) or deliver any type of energy to a patient (e.g., LASER, ultrasound), or dermabrasion devices. FDA considered comments received on the draft guidance that appeared in the *Federal Register* of September 15, 2017 (82 FR 43383). FDA revised the guidance as appropriate in response to the comments. Further, the guidance was revised to account for a De Novo request that was granted since issuance of the draft, which classified microneedling devices for aesthetic use into class II subject to premarket notification requirements under section 510(k) of the FD&C Act ((21 U.S.C. 360(k)) and special controls. The classification is codified at 21 CFR 878.4430.

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 “Regulatory

¹ On September 23, 2020, FDA published a proposed rule to amend its intended use regulations for medical products (21 CFR 201.128 and 801.4) to better reflect the Agency’s current practices in evaluating whether a product is intended for use as a drug or device. As described in the proposed rule, FDA’s longstanding position is that, in evaluating a product’s intended use, any relevant source of evidence may be considered, including a variety of direct and circumstantial evidence. 85 Fed. Reg. 59718, 59721 (Sept. 23, 2020).

Considerations for Microneedling Products.” 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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. 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 “Regulatory Considerations for Microneedling Products” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1500036 to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no 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 and guidance have been approved by OMB as listed in the following table:

21 CFR Part; Guidance; or FDA Form	Topic	OMB Control No.
807, subpart E	Premarket notification	0910-0120
“De Novo Classification Process (Evaluation of Automatic Class III Designation)”	De Novo classification process	0910-0844
“Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and	Q-submissions	0910-0756

Meetings with Food and Drug Administration Staff ⁷		
800, 801, and 809	Medical Device Labeling Regulations	0910-0485

Dated: November 5, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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