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# **Regulatory Considerations for Microneedling Products**

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## **Guidance for Industry and Food and Drug Administration Staff**

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For questions about this document, contact the OPEQ: Office of Product Evaluation and Quality, OHT4: Office of Surgical and Infection Control Devices, DHT4B: Division of Infection Control and Plastic and Reconstructive Surgery Devices, at (301) 796-6970.



**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health**

# Preface

## Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to <https://www.regulations.gov> . Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2017-D-4792. Comments may not be acted upon by the Agency until the document is next revised or updated.

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# Regulatory Considerations for Microneedling Products

## Guidance for Industry and Food and Drug Administration Staff

*This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. 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. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.*

### I. Introduction

This guidance is being issued to assist industry in understanding when a microneedling product is a device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (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. This document also provides information on the regulatory pathway to market for microneedling devices for aesthetic use.

Throughout this guidance document, the term “we” refers to FDA staff from CDRH. “You” and “your” refers to the sponsor.

FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

### II. Scope

This guidance addresses certain “microneedling products,” which 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. The needles<sup>1</sup> are incorporated into the body of an instrument that facilitates rolling or stamping of

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<sup>1</sup> For the purposes of this guidance document, the term “needles” refers to any configuration of needles, “micro-protrusion” tips, or pins.

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these needles across or into the skin. For example, the needles may be attached to a cylinder that is rolled across the skin, attached perpendicular to a flat surface that is applied to the skin in a “stamping” fashion, or arranged in an array on the tip of a pen-shaped instrument. The application of needles to skin may be done manually, or motorized where the depth and speed of penetration of needles into the skin can be controlled. Other generic terms used to describe microneedling products include: microneedling or needling instruments, needlers, dermal rollers, microneedle rollers, microneedle stamps, dermal stamps, and variations thereof.

Microneedling products have a wide range of uses from facilitating skin exfoliation and improvement of the appearance of skin, to treatment of scars, wrinkles, and other skin conditions (e.g., acne). In addition, these products may be for single use or multiple use for a single or multiple users, and include, or have available separately, cleaning solutions, additional needle cartridges, and/or additional tips.

Microneedling products have also been promoted with topically applied substances such as creams, ointments, gels, vitamin solutions, drugs, or blood products (e.g., platelet-rich plasma), which may be packaged together with the microneedling product or available separately where the microneedling product provides instructions for use with such topical products. Such microneedling products may be combination products under 21 CFR 3.2(e), which would be regulated by the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and/or the Center for Devices and Radiological Health (CDRH). Microneedling combination products are outside the scope of this guidance; manufacturers of such combination products should contact the Office of Combination Products (OCP) for additional information regarding the regulation of these products.<sup>2</sup>

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), and dermabrasion devices are also outside the scope of this guidance.

Certain microneedling products are devices, whereas others are not. See sections IV and V for more information. Sections VII.1 and VII.2 of this guidance provide examples of microneedling products that would be devices and that would not be devices, respectively.

The guidance also covers the regulation of certain microneedling devices. Specifically, microneedling devices for aesthetic use are classified as class II devices under 21 CFR 878.4430. In addition, note that microneedling devices are different than dermabrasion devices, which are not within the scope of this guidance. Dermabrasion devices are classified as class I devices under 21 CFR 878.4800 (manual) and 21 CFR 878.4820 (motorized) and are exempt from the premarket notification (510(k)) process under section 510(k) of the FD&C Act, 21 U.S.C. §

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<sup>2</sup> For information on combination products, please refer to the Office of Combination Products webpage at <https://www.fda.gov/about-fda/office-clinical-policy-and-programs/office-combination-products>

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360(k), and 21 CFR part 807, subpart E, subject to the limitations in 21 CFR 878.9. According to CDRH's 1999 guidance document "[Guidance for Dermabrasion Devices](#),"<sup>3</sup> dermabrasion devices are defined as "devices with indications for general dermabrasion, scar revision, acne scar revision, and tattoo removal." Dermabrasion devices utilize abrasion substrates such as brushes, rasps, and burrs that are intended to abrade or remove layers of the skin via shear forces. In contrast, microneedling devices utilize a substrate of needles. Although some dermabrasion devices and microneedling devices may have the same or similar intended uses, as identified above, microneedling devices have different technological characteristics and operate via different modes of action compared to dermabrasion devices which raise different questions of safety and effectiveness. In addition, microneedling devices may have intended uses that are different from those of dermabrasion devices.

### **III. Definitions**

The following definitions are intended to be used within the context of this guidance and are not necessarily applicable to any context beyond this document.

**Stratum corneum:** The stratum corneum is the superficial or outer layer of the epidermis, consisting of several layers of flat, keratinized, non-viable, peeling cells. The stratum corneum is a dead cell layer of skin, as opposed to living layers of skin.

**Exfoliation:** Exfoliation is the detachment and shedding of superficial dead cells of the epidermis, i.e., the stratum corneum.

**Living layers of skin:** Living layers of skin are layers of live cells and surrounding tissues (e.g., connective tissue) within the epidermis, dermis, and subcutis, including hair follicles and glandular structures. Living layers of skin exclude the stratum corneum.

**Dermabrasion:** Dermabrasion is the abrading or eroding of skin via shear forces with abrasive substrates such as brushes, rasps, corundum, and burrs.

### **IV. Microneedling Products That Are Devices**

#### **A. Statutory Definition of a Device**

Under section 201(h) of the FD&C Act, a device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory which is:

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

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<sup>3</sup> Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-dermabrasion-devices-guidance-industry>.

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(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animal, or

(3) intended to affect the structure or any function of the body of man or other animal, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Whether a microneedling product is a device depends, in part, on whether it is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or intended to affect the structure or any function of the body. A product's intended use refers to the "objective intent" of those legally responsible for the labeling of a product,<sup>4</sup> which is determined by their expressions or may be determined by considering the circumstances surrounding the distribution of a product.<sup>5</sup> This objective intent may be shown, for example, by the claims made by a firm of a microneedling product, and from other relevant sources.

### **B. Determining Whether a Microneedling Product Is a Device**

FDA may consider the following, among other relevant sources, in determining whether a microneedling product is a device under the FD&C Act:

#### **1. Firm's Claims and Statements**

FDA may consider, among other things, any written or oral claims or statements in any label, labeling, advertising, and/or promotion of a microneedling product by or on behalf of a firm in determining whether a microneedling product is intended to cure, mitigate, treat or prevent disease or affect the structure or function of the body. Further, FDA considers claims or statements that indicate penetration or some effect beyond the stratum corneum into living layers of skin by such products to be evidence of a firm's intent to affect the structure or function of the body. The stratum corneum is a dead layer of skin that is naturally shed through the desquamation process. Therefore, claims or statements regarding the removal of the stratum corneum are not considered an intent to affect the structure or function of the body. In contrast, explicitly or implicitly claiming or stating that a microneedling product penetrates living layers of skin (e.g., epidermis and dermis) would be considered an intent to affect the structure or function of the body. The following are examples of claims or statements associated with microneedling products that FDA believes would generally cause the product to meet the device definition:

- Treats scars (e.g., acne scars, atrophic scars, hypertrophic scars, burn scars)
- Treats wrinkles and deep facial lines

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<sup>4</sup> For the purposes of this guidance document, the term "firm" is used to refer to "persons legally responsible for the labeling of devices" under 21 CFR 801.4 as a convenience throughout the guidance.

<sup>5</sup> See 21 CFR 801.4.

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- Treats cellulite and stretch marks
- Treats dermatoses
- Treats acne
- Treats alopecia (hair loss)
- Stimulates collagen production
- Stimulates angiogenesis
- Promotes wound healing

### **2. Product Design and Technological Characteristics/Features**

In addition to examining a firm's claims and statements, FDA may consider the design and technological characteristics/features of a microneedling product in determining whether a microneedling product is a device under the FD&C Act. Specifically, FDA considers needle penetration beyond the stratum corneum as a result of the design or technology of a microneedling product as evidence that it may be "intended to affect the structure or any function of the body" under section 201(h) of FD&C Act. In considering the design and technological characteristics of these products, FDA may evaluate the following:

- Needle length and arrangement and whether the specifications facilitate penetration into living layers of skin
- Needle sharpness and whether that facilitates penetration into living layers of skin
- Degree of control of manual or motorized microneedling products over the movement of needles and depth of penetration into living layers of skin

Information regarding design and technological characteristics may be found in various places, including the product's specifications, directions for use, or other materials.

## **V. Microneedling Products That Are Not Devices**

Microneedling products that are not intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, and that are not intended to affect the structure or any function of the body, are not devices under section 201(h) of the FD&C Act. For example, generally, microneedling products that do not penetrate living skin (e.g., epidermal and dermal layers of the skin) and claim only to do the following would not be devices:

- facilitate exfoliation of the skin (i.e., disruption or removal of the stratum corneum)
- improve the appearance of skin
- give skin a smoother look and feel
- give skin a luminous look

In general, such microneedling products would not be devices; however, the products may still be subject to other requirements of the FD&C Act or other Federal statutes or regulations administered by other Federal agencies.



## **VI. Classification of Certain Microneedling Devices**

Microneedling devices for aesthetic use are classified as class II devices under 21 CFR 878.4430, subject to premarket notification (510(k)) and special controls outlined in the classification regulation (see 21 CFR 878.4430(b)(1)-(10)). Under 21 CFR 878.4430, a microneedling device for aesthetic use is identified as a device using one or more needles to mechanically puncture and injure skin tissue for aesthetic use. This classification does not include devices intended for transdermal delivery of topical products such as cosmetics, drugs, or biologics. FDA classified microneedling devices for aesthetic use into class II under section 513(f)(2) of the FD&C Act, also referred to as the De Novo classification process. This process provides a pathway to class I or class II classification for devices for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device. Additional recommendations on information to include in a 510(k) submission for a microneedling device for aesthetic use is provided in response to Question 3 below.

## **VII. Questions and Answers**

### **1. What are examples of microneedling products that would be devices?**

As discussed above, microneedling products are regulated as devices if they are intended to diagnose disease or other conditions, or cure, mitigate, treat, or prevent disease, or to affect the structure or function of the body, as defined under section 201(h) of the FD&C Act. The following are examples of microneedling products that FDA believes generally would be regulated as devices:

- a) A manual microneedling product with short, blunt needles where the firm makes claims that the product is intended to exfoliate, give skin a luminous look, stimulate collagen production, and treat wrinkles

In spite of the exfoliation and “give skin a luminous look” claims in this first example, the firm also makes claims that the microneedling product is intended to stimulate collagen production and treat wrinkles (i.e., affect the structure or function of skin); therefore, the product would be subject to FDA regulation as a device.

- b) A motorized microneedling product with sharp needles that penetrate living layers of the skin, where the firm makes claims that the product is intended to make skin smoother by penetrating the skin to stimulate healing response and formation of new tissue

This second example illustrates how FDA considers the design and technological characteristics of a microneedling product, in conjunction with claims by the firm, to determine whether the product is a device. Here, the microneedling product is intended to affect the structure and function of the body. Although making skin smoother may not necessarily require an effect on the structure or function of the body, such as through the

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removal or disruption of the stratum corneum, the firm makes claims that the product here is intended to penetrate living layers of the skin and designed the product to achieve this effect. Therefore, it would be subject to FDA regulation as a device.

## **2. What are examples of microneedling products that would not be devices?**

As discussed above, microneedling products that are not intended to diagnose disease or other conditions, or cure, mitigate, treat or prevent disease and that are not intended to affect the structure or any function of the body are not devices, as defined under section 201(h) of FD&C Act. The following are examples of microneedling products that FDA believes generally would not be devices:

- a) A microneedling product with short, blunt needles or “micro-protrusion” tips that do not penetrate living layers of skin and for which the firm claims that the product is intended to facilitate skin exfoliation
- b) A microneedling product with short, densely packed needles that are not designed to penetrate living layers of skin and for which the firm claims that the product is intended to give skin a smoother look and feel

In both examples, the products would not be devices. In these examples, the microneedling products are intended to be used to facilitate skin exfoliation and to give skin a smoother look and feel. Furthermore, the products are designed such that they would not penetrate living layers of skin due to the needle length, blunt needle tips, and/or densely packed needles.

## **3. I have determined my microneedling product is a device regulated by CDRH. What are my next steps?**

Microneedling devices for aesthetic use were classified as class II devices under 21 CFR 878.4430<sup>6</sup> as part of a De Novo classification request (DEN160029).<sup>7</sup>

Manufacturers wishing to market their microneedling device for aesthetic use should submit a premarket notification (510(k))<sup>8</sup> submission demonstrating substantial equivalence of their device to a legally marketed predicate microneedling device and compliance with the special controls as codified in 21 CFR 878.4430.

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<sup>6</sup> Granting order available at [https://www.accessdata.fda.gov/cdrh\\_docs/pdf16/DEN160029.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf16/DEN160029.pdf) and announced in the Federal Register on June 8, 2018 (83 FR 26575).

<sup>7</sup> DEN160029 Decision Summary is available at [https://www.accessdata.fda.gov/cdrh\\_docs/reviews/DEN160029.pdf](https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN160029.pdf).

<sup>8</sup> More information on the 510(k) review process is available in the FDA guidance document “The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]” (“the 510(k) program guidance”), accessible at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k>.

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The special controls described in 21 CFR 878.4430(b)(1)-(10) mitigate the identified risks to health associated with microneedling devices for aesthetic use including adverse tissue reaction; cross-contamination and infection; electrical shock or electromagnetic interference with other devices; and damage to underlying tissue including nerves and blood vessels, scarring, and hyper/hypopigmentation due to exceeding safe penetration depth, mechanical failure, or software malfunction.

The 510(k) submission should identify the predicate device to which the new microneedling device is compared. For a microneedling device that has new or modified indications for use and/or different technological characteristics when compared to the predicate device, FDA may request clinical performance data in addition to non-clinical testing if needed to make a substantial equivalence determination.<sup>9</sup> For those submissions where clinical data is necessary to demonstrate substantial equivalence, we recommend considering the following when designing a clinical study:

- i) The clinical study protocol should generally ensure that enrolled subjects are representative of the clinical population that the device is intended to treat. This should be reflected in the inclusion and exclusion criteria developed for the study.
- ii) Safety data should generally be collected to support the safe use of the device. Such data should characterize the risks of infection, nerve and blood vessel damage, scar formation, hyper-/hypo-pigmentation, skin inflammation, allergic reactions, skin irritation, and other adverse events related to the use of the device.
- iii) The proposed primary effectiveness endpoint should generally be developed to align with the proposed indications for use for your device. Effectiveness should be measured using a method that minimizes subjectivity or bias. FDA recommends use of validated measurement tools to assess device effectiveness.
- iv) The follow-up period should ensure a reasonable assessment of the short-term and long-term performance of the device, as it relates to the safety and effectiveness endpoints as outlined above.

As a resource for designing clinical studies, FDA recommends reviewing the guidance document “[Design Considerations for Pivotal Clinical Investigations for Medical Devices](#).”<sup>10</sup>

If you have further questions regarding a proposed premarket submission, you may contact FDA via the Pre-Submission process. For more information regarding the Pre-Submission program, refer to the guidance document “[Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program](#).”<sup>11</sup>

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<sup>9</sup> Please refer to the 510(k) program guidance discussed above for more information on the 510(k) review process.

<sup>10</sup> Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-considerations-pivotal-clinical-investigations-medical-devices>.

<sup>11</sup> Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program>.