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Regulatory Considerations for Microneedling Devices

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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For questions about this document, contact the Office of Device Evaluation, Division of Surgical Devices, at (301) 796-6970.



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

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Preface

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Regulatory Considerations for Microneedling Devices

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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This draft guidance is being issued to assist industry in understanding when a microneedling product is a device as defined in section 201(h) of the Federal Food, Drug, and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 clarity on the regulatory pathway to market for microneedling devices.

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities.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This draft guidance addresses certain “microneedling products,” which is a generic term that encompasses instruments with common technological features that include an array of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

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33 needles¹ are incorporated into the body of an instrument that facilitates rolling or stamping of
34 these needles across or into the skin. For example, the needles may be attached to a cylinder that
35 is rolled across the skin, attached perpendicular to a flat surface which is applied to the skin in a
36 “stamping” fashion, or arranged in an array on the tip of a pen-shaped instrument. The
37 application of needles to skin may be done manually, or motorized where the depth and speed of
38 penetration of needles into the skin can be controlled. Other generic terms used to describe
39 microneedling products include: microneedling or needling instruments, needlers, dermal rollers,
40 microneedle rollers, microneedle stamps, dermal stamps, and variations thereof.

41
42 Microneedling products have a wide range of intended uses from facilitating skin exfoliation,
43 improvement of the appearance of skin to treatment of scars, wrinkles, and other skin conditions
44 (e.g., acne). In addition, these products may be indicated for single use or multiple use for a
45 single or multiple users, and include, or have available separately, cleaning solutions, additional
46 needle cartridges, and/or additional tips.

47
48 Microneedling products have also been promoted with topically applied substances such as
49 creams, ointments, gels, vitamin solutions, drugs, or blood products (e.g., platelet-rich-plasma),
50 which are either packaged together with the microneedling product or available separately where
51 the microneedling product provides instructions for use with such topical products. Such
52 microneedling products may be combination products under 21 CFR 3.2(e), which would be
53 regulated by the Center for Drug Evaluation and Research (CDER), the Center for Biologics
54 Evaluation and Research (CBER), and/or the Center for Devices and Radiological Health
55 (CDRH). Microneedling combination products are outside the scope of this guidance;
56 manufacturers of such combination products should contact the Agency for additional
57 information regarding the regulation of these products.²

58
59 Acupuncture needles, hypodermic needles or other needles for injection, tattoo machine needles,
60 and needle probes that emit any type of energy (e.g., radio-frequency needles) or deliver any type
61 of energy to a patient (e.g., LASER, ultrasound) are also outside the scope of this guidance.

62
63 Certain microneedling products are devices, whereas others are not. See sections IV and V for
64 more information. In addition, FDA is not aware of any microneedling devices that are
65 preamendment devices (i.e., available before the enactment of the Medical Device Amendments
66 of 1976) and FDA has not yet classified these devices. See section VI for more information on
67 the De Novo classification process.

68
69 Microneedling devices are different than dermabrasion devices. Dermabrasion devices are
70 classified as class I devices under 21 CFR 878.4800 (manual) and 21 CFR 878.4820 (motorized)

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

² For information on combination products, please refer to the Office of Combination Products webpage at <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/OfficeofScienceandHealthCoordination/ucm2018184.htm>.

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71 and are exempt from the premarket notification (510(k)) process under section 510(k) of the
72 FD&C Act, 21 U.S.C. § 360(k), and 21 CFR part 807, subpart E, subject to the limitation in 21
73 CFR 878.9. According to CDRH’s 1999 guidance document, “Guidance for Dermabrasion
74 Devices”
75 (<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocu>
76 [ments/ucm073789.pdf](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocu)), dermabrasion devices are defined as “devices with indications for
77 general dermabrasion, scar revision, acne scar revision, and tattoo removal.” Dermabrasion
78 devices utilize abrasion substrates such as brushes, rasps, and burrs that are intended to abrade
79 and remove layers of the skin via shear forces. In contrast, microneedling devices utilize a
80 substrate of needles. Although dermabrasion devices and microneedling devices may have the
81 same or similar intended uses, as identified above, microneedling devices have technological
82 characteristics and operate via modes of action that are different from those of dermabrasion
83 devices that raise different questions of safety and effectiveness. In addition, microneedling
84 devices may have intended uses that are different from those of dermabrasion devices.

85 **III. Definitions**

86
87 The following definitions are intended to be used within the context of this draft guidance and
88 are not applicable to any context beyond this document.
89

90 **Stratum corneum:** The stratum corneum is the superficial or outer layer of the epidermis,
91 consisting of several layers of flat, keratinized, non-viable, peeling cells. The stratum corneum is
92 a dead cell layer of skin, as opposed to living layers of skin.
93

94 **Exfoliation:** Exfoliation is the detachment and shedding of superficial dead cells of the
95 epidermis, i.e., the stratum corneum.
96

97 **Living layers of skin:** Living layers of skin are layers of live cells and surrounding tissues (e.g.,
98 connective tissue) within the epidermis, dermis, and subcutis, including hair follicles and
99 glandular structures. Living layers of skin exclude the stratum corneum.
100

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

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

104

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

106

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

110

- 111 • intended for use in the diagnosis of disease or other conditions, or in the cure,
112 mitigation, treatment, or prevention of disease, or

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- 113
114 • intended to affect the structure or any function of the body of man,
115
116 and which does not achieve its primary intended purposes through chemical action within
117 or on the body of man and which is not dependent upon being metabolized for the
118 achievement of its primary intended purposes.
119

120 Whether a microneedling product is a device, in part, depends on whether it is intended for use in
121 the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of
122 disease, or intended to affect the structure or any function of the body. A product’s intended use
123 refers to the “objective intent” of those legally responsible for the labeling of a product,³ which is
124 determined by their expressions or may be determined by considering the circumstances
125 surrounding the distribution of a product.⁴ This objective intent may be shown, for example, by
126 the claims made by a firm of a microneedling product, and from other relevant sources.
127

128 **B. Determining Whether a Microneedling Product Is a**
129 **Device**
130

131 FDA may take into account the following, among other relevant sources, in determining whether
132 a microneedling product is a device under the FD&C Act:
133

134 **1. Firm’s Claims**
135

136 FDA may consider the written or oral statements in any label, labeling, advertising,
137 and/or promotion of a microneedling product by or on behalf of a firm in determining
138 whether a microneedling product is intended to cure, mitigate, treat or prevent disease or
139 affect the structure or function of the body. Further, FDA considers claims that indicate
140 penetration or some effect beyond the stratum corneum into living layers of skin by such
141 products to be evidence of a firm’s intent to affect the structure or function of the body.
142 The stratum corneum is a dead layer of skin that is naturally shed through the
143 desquamation process. Therefore, claims regarding the removal of the stratum corneum
144 are not considered an intent to affect the structure or function of the body. In contrast,
145 explicitly or implicitly claiming that a microneedling product penetrates living layers of
146 skin (e.g., epidermis and dermis), would be an intent to affect the structure or function of
147 the body. The following are examples of claims associated with microneedling products
148 that meet the device definition:
149

- 150 • Treats scars (e.g., acne scars, atrophic scars, hypertrophic scars, burn scars)
151 • Treats wrinkles and deep facial lines
152 • Treats cellulite and stretch marks

³ 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.

⁴ See 21 CFR 801.4.

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- 153 • Treats dermatoses
- 154 • Treats acne
- 155 • Treats alopecia (hair loss)
- 156 • Stimulates collagen production
- 157 • Stimulates angiogenesis
- 158 • Promotes wound healing

159
160 **2. Device Design and Technological Characteristics/Features**

161
162 In addition to examining a firm’s claims, FDA may consider the design and
163 technological characteristics/features of a microneedling product as a relevant source of
164 information regarding intended use. Specifically, FDA considers needle penetration
165 beyond the stratum corneum as a result of the design or technology of a microneedling
166 product as evidence that it may be intended to “affect the structure or any function of the
167 body.” In considering the design and technology of these products, FDA evaluates the
168 following:

- 169
- 170 • Needle length and arrangement and whether the specifications facilitate
- 171 penetration into living layers of skin
- 172 • Needle sharpness and whether that facilitates penetration into living layers of skin
- 173 • Degree of control of manual or motorized microneedling products over the
- 174 movement of needles and depth of penetration into living layers of skin

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

176
177 Microneedling products which are not intended for use in the diagnosis of disease or other
178 conditions, or in the cure, mitigation, treatment or prevention of disease, and which are not
179 intended to affect the structure or any function of the body, are not devices under the FD&C Act.
180 For example, generally, microneedling products that do not penetrate living skin (e.g., epidermal
181 and dermal layers of the skin) and claim only to do the following would not be devices:

- 182
- 183 • facilitate exfoliation of the skin (i.e., disruption of the stratum corneum)
- 184 • improvement in the appearance of skin
- 185 • give skin a smoother look and feel
- 186 • give skin a luminous look
- 187

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

191 **VI. Classification of Microneedling Devices**

192
193 At the time of issuance of this draft guidance, microneedling devices do not fall within any
194 classification regulation, and there is no legally marketed predicate device upon which to base a

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195 determination of substantial equivalence. Such devices are of a new type that FDA has not
196 previously classified based on the criteria at section 513(a)(1) of the FD&C Act, 21 U.S.C. §
197 360c(a)(1), and are statutorily classified into class III by operation of section 513(f)(1) of the
198 FD&C Act. However, FDA believes that these devices may be suitable for classification under
199 section 513(f)(2) of the FD&C Act, also referred to as the De Novo classification process. This
200 process provides a pathway to class I or class II classification for low-moderate risk devices for
201 which general controls or general and special controls provide a reasonable assurance of safety
202 and effectiveness, but for which there is no legally marketed predicate device. Under section
203 513(f)(2)(A)(ii) of the FD&C Act, a manufacturer of a microneedling device may request FDA
204 to classify its device based on the criteria set forth in section 513(a)(1) of the FD&C Act without
205 first submitting a 510(k). If a De Novo request is granted for a microneedling device, the specific
206 device and device type would be classified in class I or II, and may be marketed immediately and
207 serve as a predicate for future devices. For additional information, please visit FDA’s webpage at
208 [http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CD](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm232269.htm)
209 [RHTransparency/ucm232269.htm](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm232269.htm).

210 VII. Questions and Answers

211

212 1) What are examples of microneedling products that would be 213 devices?

214 As discussed above, microneedling products are regulated as devices if they are intended to
215 diagnose disease or other conditions, or cure, mitigate, treat, or prevent disease, or to affect
216 the structure or function of the body. The following are examples of microneedling products
217 that would be regulated as devices:

218

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

222

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

227

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

231

232 This second example illustrates how FDA considers the technology and design of a
233 microneedling product, in conjunction with statements by the firm to determine whether the
234 product is a device. Here, the microneedling product is intended to affect the structure and
235 function of the body. Although making skin smoother may not necessarily require an effect
236 on the structure or function of the body, such as through the removal or disruption of the

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

240

241 **2) What are examples of microneedling products that would not be**
242 **devices?**

243 As discussed above, microneedling products which are not intended to diagnose disease or
244 other conditions, or cure, mitigate, treat or prevent disease and which are not intended to
245 affect the structure or any function of the body are not devices. For example, the following
246 products would not be devices:

247

248 a) A microneedling product with short, blunt needles or “micro-protrusion” tips that do not
249 penetrate living layers of skin and for which the firm claims that the product is intended
250 to facilitate skin exfoliation

251

252 b) A microneedling product with short, densely packed needles that are not designed to
253 penetrate living layers of skin and for which the firm claims that the product is intended
254 to give skin a smoother look and feel

255

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

261

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

264 At the time of issuance of this draft guidance, there is no existing classification regulation for
265 microneedling devices. However, FDA believes that these devices may obtain marketing
266 authorization as class I or class II devices under the De Novo classification process (see
267 section VI, above).

268 To facilitate review, the De Novo request should include all necessary information to
269 demonstrate a reasonable assurance of the safety and effectiveness of the device. The De
270 Novo request should identify the benefits and risks of the device and the general controls or
271 general and special controls needed to assure safety, such as mitigation measures to any
272 identified risks to health, and effectiveness. Data should be provided which demonstrate that
273 general controls or general and special controls support a classification of class I or class II.
274 Based on currently available information, FDA considers risks associated with microneedling
275 devices to include infection, nerve and blood vessel damage, disease transmission between
276 users, scar formation, hyperpigmentation, skin inflammation, allergic reactions, and skin
277 irritation. Additional risks may be identified depending on the technological characteristics
278 and intended uses of the specific microneedling device.

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279 The following information should be considered for inclusion in your De Novo request. This
280 list is not intended to be comprehensive regarding the content to include in a De Novo
281 request for a microneedling device. Additional information and testing data may be needed
282 depending on the technological characteristics and intended uses of the specific
283 microneedling device.

- 284 a) Information regarding the technological characteristics and performance of your device,
285 including, but not limited to:
- 286 i) Representative engineering drawing(s), schematics, illustrations and/or figures of
287 the device that are clear, legible, labeled, and include dimensions
 - 288 ii) Consumables and disposable items included with the device, including additional or
289 extra needle heads, sleeves, etc.
 - 290 iii) Needle characteristics, including materials, length, adjustability, sharpness, and
291 geometry
 - 292 iv) Biocompatibility information; see FDA’s guidance document “Use of International
293 Standard ISO-10993-1, ‘Biological evaluation of medical devices - Part 1:
294 Evaluation and testing within a risk management process’”
295 (<http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm348890.pdf>)
296
 - 297 v) Proposed labeling for your device, including package labeling and instructions for
298 use
 - 299 vi) Usability testing of your device with an appropriate user population; see FDA’s
300 guidance document “Applying Human Factors and Usability Engineering to
301 Medical Devices”
302 (<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm259760.pdf>)
303
 - 304 vii) Sterilization information; see FDA’s guidance document “Submission and Review
305 of Sterility Information in Premarket Notification (510(k)) Submissions for Devices
306 Labeled as Sterile”
307 (<http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm109897.pdf>)
308
 - 309 viii) Cleaning or disinfection information, if the device is reusable; see FDA’s guidance
310 document “Reprocessing Medical Devices in Health Care Settings: Validation
311 Methods and Labeling”
312 (<http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf>)
313
 - 314 ix) If applicable, information regarding the motorized components or aspects of your
315 device, including testing to mitigate risks associated with the mechanism of use
316 (e.g., electrical safety, fluid ingress, electromagnetic compatibility)
 - 317 x) If applicable, information regarding software; see FDA’s guidance document
318 “Guidance for the Content of Premarket Submissions for Software Contained in

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319 Medical Devices”
320 (<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089593.pdf>)
321

- 322 b) Clinical data may be necessary to demonstrate a reasonable assurance of the safety and
323 effectiveness of a microneedling device. We recommend considering the following when
324 designing a clinical study:
- 325 i) The clinical study protocol should ensure that enrolled subjects are representative of
326 the clinical population that the device is intended to treat. This should be reflected
327 in the inclusion and exclusion criteria developed for the study.
 - 328 ii) Safety data should be collected to support the safe use of the device. Such data
329 should characterize the risks of infection, nerve and blood vessel damage, scar
330 formation, hyperpigmentation, skin inflammation, allergic reactions, skin irritation,
331 and other potential adverse events related to the use of the device.
 - 332 iii) The proposed primary effectiveness endpoint should be developed to support the
333 proposed indications for use for your device. Effectiveness should be measured
334 using a method that minimizes subjectivity or bias. FDA recommends use of
335 validated measurement tools to assess device effectiveness.
 - 336 iv) The follow-up period should ensure a reasonable assessment of the short-term and
337 long-term safety and effectiveness of the device.

338 Given the risks associated with these devices, consideration should be given as to
339 whether the clinical study will be a Significant Risk device study. For additional
340 information, please see the guidance document “Significant Risk and Nonsignificant Risk
341 Medical Device Studies”
342 (<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf>).

343 As a resource for designing clinical studies, FDA recommends reviewing the guidance
344 document “Design Considerations for Pivotal Clinical Investigations for Medical
345 Devices”
346 (<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM373766.pdf>).
347

348 If you have further questions regarding a proposed De Novo request, you may contact FDA
349 via the Pre-Submission process. For more information regarding the Pre-Submission
350 program, please refer to the guidance document “Requests for Feedback on Medical Device
351 Submissions: The Pre-Submission Program and Meetings with Food and Drug
352 Administration Staff”
353 (<http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf>).
354