



March 1, 2018

Bellus Medical, LLC
Jennifer Block
Director of Quality and Regulatory
4505 Excel Parkway
Suite 100
Addison, TX 75001

Re: DEN160029
Trade/Device Name: SkinPen Precision System
Regulation Number: 21 CFR 878.4430
Regulation Name: Microneedling device for aesthetic use
Regulatory Class: Class II
Product Code: QAI
Dated: July 1, 2016
Received: July 5, 2016

Dear Jennifer Block:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the SkinPen Precision System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

SkinPen® Precision System is a microneedling device and accessories intended to be used as a treatment to improve the appearance of facial acne scars in adults aged 22 years or older.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the SkinPen Precision System, and substantially equivalent devices of this generic type, into Class II under the generic name microneedling device for aesthetic use.

FDA identifies this generic type of device as:

Microneedling device for aesthetic use. A microneedling device for aesthetic use is 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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified

under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register classifying the device type.

On July 5, 2016, FDA received your De Novo requesting classification of the SkinPen Precision System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the SkinPen Precision System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the SkinPen Precision System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	Mitigation Measures
Adverse tissue reaction	Biocompatibility evaluation Labeling
Cross-contamination and infection	Sterilization validation Reprocessing validation Non-clinical performance testing Shelf life testing Labeling
Electrical shock or electromagnetic interference with other devices	Electromagnetic compatibility testing Electrical safety testing Labeling
Damage to underlying tissue including nerves and blood vessels, scarring, and hyper/hypopigmentation due to <ul style="list-style-type: none"> • Exceeding safe penetration depth • Mechanical failure • Software malfunction 	Non-clinical performance testing Technological characteristics Shelf life testing Labeling Software verification, validation, and hazard analysis

In combination with the general controls of the FD&C Act, the microneedling device for aesthetic use is subject to the following special controls:

- (1) The technical specifications and needle characteristics must be identified, including needle length, geometry, maximum penetration depth, and puncture rate.
- (2) Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
 - (i) Accuracy of needle penetration depth and puncture rate;

- (ii) Safety features built into the device to protect against cross-contamination, including fluid ingress protection; and
 - (iii) Identification of the maximum safe needle penetration depth for the device for the labeled indications for use.
- (3) Performance data must demonstrate the sterility of the patient-contacting components of the device.
 - (4) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the intended shelf life.
 - (5) Performance data must demonstrate the electrical safety and electromagnetic compatibility (EMC) of all electrical components of the device.
 - (6) Software verification, validation, and hazard analysis must be performed for all software components of the device.
 - (7) The patient-contacting components of the device must be demonstrated to be biocompatible.
 - (8) Performance data must validate the cleaning and disinfection instructions for reusable components of the device.
 - (9) Labeling must include the following:
 - (i) Information on how to operate the device and its components and the typical course of treatment;
 - (ii) A summary of the device technical parameters, including needle length, needle geometry, maximum penetration depth, and puncture rate;
 - (iii) Validated methods and instructions for reprocessing of any reusable components;
 - (iv) Disposal instructions; and
 - (v) A shelf life.
 - (10) Patient labeling must be provided and must include:
 - (i) Information on how the device operates and the typical course of treatment;
 - (ii) The probable risks and benefits associated with use of the device; and
 - (iii) Post-operative care instructions.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a

premarket notification containing information on the microneedling device for aesthetic use they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Kimberly Ferlin, Ph.D. at 240-402-1834.

Sincerely,

Angela C. Krueger
Deputy Director, Engineering and Science Review (Acting)
Office of Device Evaluation
Center for Devices and Radiological Health