October 22, 2021

NC8, Inc. (Revelle Aesthetics, Inc.)
Mellissa Viotti
Sr. Director, Quality & Regulatory Affairs
2570 W. El Camino Real, Suite 310
Mountain View, California 94040

Re: K212399
Trade/Device Name: Aveli
Regulation Number: 21 CFR 878.4790
Regulation Name: Powered Surgical Instrument for Improvement in the Appearance of Cellulite
Regulatory Class: Class II
Product Code: OUP
Dated: July 30, 2021
Received: August 2, 2021

Dear Mellissa Viotti:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212399

Device Name
Avéli

Indications for Use *(Describe)*
Avéli is indicated for temporary reduction in the appearance of cellulite in the buttocks and thigh areas of adult females as supported by clinical data demonstrating benefits through three months of observation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Submitter Information

Submitter: NC8, Inc. (name changed to Revelle Aesthetics, Inc.)
2570 W. El Camino Real, Suite 310
Mountain View, CA 94040

Contact: Melissa Viotti
Senior Director, Quality and Regulatory Affairs
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Date Summary Prepared: September 29, 2021

Subject Device Information

Device Trade Name: Avéli(TM)

Common Name: Precision Cellulite Release Device

Regulation Number: 21 CFR 878.4790

Product Code: OUP

Predicate Device Information

Predicate Device: The Cellfina System (K192185)

Predicate Device Manufacturer: Ulthera Inc. (now Merz Aesthetics)

Device Description

Avéli is a sterile, single-use manual instrument that cuts fibrous tissue (septa) beneath moderate to severe cellulite for temporary reduction in the appearance of cellulite in the buttocks and thigh areas of adult females. The device consists of a handle and a distal end. The handle houses components used to actuate the moving parts at the distal end of the device. The distal end of the device is advanced into subcutaneous tissue through a small incision to a procedure location. An integrated light source provides illumination and allows the user to track and advance to the procedure location. The distal end of the device contains a blunt link and a sharpened link forming a distal hook. When the handle is moved in a retrograde fashion, the distal hook next to a fibrous septum captures the septum resulting in tugging. The user feels the resistance, confirming that a septum under a cellulite depression has been identified. The user then engages a sharpened link to be exposed at the distal end of the device. The user applies additional retrograde motion to sever the fibrous septum, and then retracts the sharpened link and the blunt link into the device, allowing removal without further tissue capture. The step is repeated for each visible cellulite depression.

Indications for Use

Avéli is indicated for temporary reduction in the appearance of cellulite in the buttocks and thigh areas of adult females as supported by clinical data demonstrating benefits through three months of observation.

Comparison of Technological Characteristics with the Predicate Device

A comparison of Avéli to the predicate device is provided in the table below. This table demonstrates that Avéli is substantially equivalent to the predicate device for its indication for use, performance, and technological characteristics.

Device Name	**SUBJECT DEVICE** **Avéli**	**PREDICATE DEVICE** **The Cellfina System**
510(k) Number	TBD (K212399)	K192185
Manufacturer	NC8, Inc. (name changed to Revelle Aesthetics, Inc.)	Merz Aesthetics (previously Ulthera, Inc.)
Device Class	II	Same, II
Regulation Number	878.4790	Same, 878.4790
Product Code	OUP	Same, OUP
Clearance Date	TBD	October 9, 2019
Intended Use	Avéli is intended for temporary reduction in the appearance of cellulite in the buttocks and thigh areas of adult females as supported by clinical data demonstrating benefits through three months of observation.	The Cellfina System is intended for long term improvement in the appearance of cellulite in the buttocks and thigh areas of adult females as supported by clinical data demonstrating no significant reduction in treatment benefits through five years of observation.
Indications for Use	Avéli is indicated for temporary reduction in the appearance of cellulite in the buttocks and thigh areas of adult females as supported by clinical data demonstrating benefits through three months of observation.	The Cellfina System is indicated for long term improvement in the appearance of cellulite in the buttocks and thigh areas of adult females as supported by clinical data demonstrating no significant reduction in treatment benefits through five years of observation.
Where Used	Clinic/Doctor's office	Same, Clinic/Doctor's office
Anatomical Site	Buttocks and thighs	Same, Buttocks and thighs

Device Name	**SUBJECT DEVICE** **Avéli**	**PREDICATE DEVICE** **The Cellfina System**
Technological Characteristics	Blade dissects soft tissue	Same, Blade dissects soft tissue
Material of Distal End Dissecting Zone	Stainless steel	Same, Stainless steel
Illumination Feature	Yes	No
Controlled Dissection	Yes	Same, Yes
Biological Effect	Controlled mechanical cutting of the fibrous tissue which contributes to the appearance of cellulite.	Same, Controlled mechanical cutting of the fibrous tissue which contributes to the appearance of cellulite.
Single Use	Yes	The blade component is single use and the motorized component is reusable
Sterile	Yes	Same, Yes
Electromagnetic Compatibility Standards	Compatible	Same, Compatible
Medical Electrical Equipment Safety Standards	Compatible	Same, Compatible

Performance Data

The following performance data were provided to verify that the subject device met all design specifications and provided support of the substantial equivalence determination.

-Verification Testing:

1) Visual Inspections
2) Dimensional Inspections
3) Functional testing including:
   - Simulated use testing
   - Force measurements
   - Tensile testing
   - Mechanical testing
   - Electrical testing
   - Optical output testing

-Electrical Safety Testing (IEC 60601-1:2005 +A1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2010 + AMD1:2013/IEC 62366-1:2020)

-Biocompatibility Testing (ISO 10993-1:2018)

-Sterilization Validation (ISO 11135-1:2014, ISO 14161:2009)

Clinical Performance Data

The *in vivo* performance of the device was evaluated in a pivotal clinical study. A prospective, non-randomized, multi-center study was conducted to evaluate the safety and effectiveness of Avéli for the treatment of cellulite in the buttock and thigh areas across nine (9) investigational sites. All participants served as their own control and underwent a single treatment with Avéli. The enrolled study population included females between the ages of 26 and 54 with moderate to severe cellulite and BMI between 19 and 30. In addition, participants were excluded that smoked or had recently quit smoking (within the last 6 months).

The primary safety endpoint was achieved. There were no Serious Adverse Events (SAE) related to the device or procedure at 30 days. No Unanticipated Adverse Device Effects (UADE) occurred in the study. Therefore, as no SAE were determined to be related to the device or procedure, the primary safety endpoint for the study was achieved. There were three adverse device effects (ADEs) that occurred in two participants: 1) an extended incision, 2) a skin laceration, and 3) a small scar following the skin laceration. Ecchymosis was reported by most participants. Many participants experienced tenderness or pain within the first 24 hours, and most returned to normal activities one day after the procedure.

The primary effectiveness endpoint was achieved. Effectiveness was evaluated by improvement assessment by independent physician evaluation of participant photographs. All reliability and repeatability measures were met and validated the methodology. The primary effectiveness endpoint was to demonstrate that the mean change (improvement) in the Cellulite Severity Score (CSS) is more than 1 for the study population, as determined by three independent, blinded physician evaluators of photos obtained before and 3-months after the investigational procedure.

Conclusion

The subject Avéli device is similar to the predicate device with respect to the principles of operation. Some technological and performance characteristics of subject device are different from some of the predicate device. Pre-clinical and clinical testing was conducted to evaluate the differences in technological and performance characteristics. Results of clinical testing have demonstrated substantial equivalence of the subject device to the predicate in terms of safety and effectiveness for the intended use.