August 5, 2022

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

Re: K221336
Trade/Device Name: Avéli
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: May 6, 2022
Received: May 9, 2022

Dear Melissa 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,

for

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)*
K221336

Device Name
Avéli

Indications for Use *(Describe)*
Avéli is indicated for long-term reduction in the appearance of cellulite in the buttocks and thigh areas of adult females as supported by clinical data demonstrating treatment benefits through one year 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: Revelle Aesthetics, Inc.
2570 W. El Camino Real, Suite 310
Mountain View, CA 94040

Contact: Melissa Viotti
Senior Director, Quality and Regulatory Affairs
Telephone and Fax: 650-336-5985
Email: mviotti@revelleax.com

Date Summary Prepared: August 5, 2022

Subject Device Information

Device Trade Name: Avéli(TM)

Common Name: Avéli(TM)

Regulation Number: 21 CFR 878.4790

Product Code: OUP

Predicate Device Information

Predicate Device: Avéli (K212399)

Predicate Device Manufacturer: NC8, Inc. (now Revelle Aesthetics)

Device Description

Avéli is a sterile, single-use manual instrument that releases fibrous tissue (septa) beneath cellulite for long-term 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 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 contains a Blade and a Blocker forming a Hook. When the Handle is moved in a retrograde fashion, the Hook next to fibrous septa captures the septa resulting in tugging. The user feels the resistance, confirming that septa under a cellulite depression have been identified and then exposes the Blade at the Distal End. The user pushes the skin distally with the free hand while maintaining the device stable or applies additional retrograde motion with the device to release the fibrous septa. The user then retracts the Blade and the Blocker into the device, allowing

removal without further tissue engagement. The user can verify all contributing septa have been released by passing through the area again with the Hook. The step is repeated for each visible cellulite depression.

Indications for Use

Avéli is indicated for long-term reduction in the appearance of cellulite in the buttocks and thigh areas of adult females as supported by clinical data demonstrating treatment benefits through one year 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 the subject device is substantially equivalent to the predicate device for its indication for use, performance, and technological characteristics.

Device Name	**SUBJECT DEVICE** **Avéli**	**PREDICATE DEVICE** **Avéli**
510(k) Number	TBD	K212399
Manufacturer	Revelle Aesthetics, Inc.	Same, NC8, Inc. (name changed to Revelle Aesthetics, Inc.)
Device Class	II	Same, II
Regulation Number	878.4790	Same, 878.4790
Product Code	OUP	Same, OUP
Clearance Date	TBD	October 22, 2021
Intended Use	Avéli is intended for long-term reduction in the appearance of cellulite in the buttocks and thigh areas of adult females as supported by clinical data demonstrating treatment benefits through one year of observation.	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.
Indications for Use	Avéli is indicated for long-term reduction in the appearance of cellulite in the buttocks and thigh areas of adult females as supported by clinical data demonstrating treatment benefits through one year of observation.	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.
Where Used	Clinic/Doctor's office	Same, Clinic/Doctor's office
Anatomical Site	Buttocks and thighs	Same, Buttocks and thighs
Technological Characteristics	Blade dissects soft tissue	Same, Blade dissects soft tissue

Device Name	SUBJECT DEVICE Avéli	PREDICATE DEVICE Avéli
Material of Distal End Dissecting Zone	Stainless steel	Same, Stainless steel
Illumination Feature	Yes	Same, Yes
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	Same, Yes
Sterile	Yes	Same, Yes
Electromagnetic Compatibility Standards	Compatible	Same, Compatible
Medical Electrical Equipment Safety Standards	Compatible	Same, Compatible

Performance Data

The following performance testing was conducted to verify that the subject device meets all design specifications in 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 Avéli 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 of 74 participants across nine (9) investigational sites in the US and Australia. All participants served as their own control and underwent a single treatment with Avéli. Participants underwent follow-up assessments at 1 day (virtual), 7 days (virtual or clinic), 30 days, 3 months, 6 months, and one year post-treatment.

The participant inclusion/exclusion criteria limited inclusion to females between the ages of 21 and 55 with moderate to severe cellulite in the thighs and/or buttocks and a body mass index (BMI) less than 30. The enrolled study population included females between the ages of 26 and 54 with moderate to severe cellulite and BMI between 19 and 29.8. In addition, participants were excluded that smoked or had recently quit smoking (within the last 6 months). The participants were asked to rate their pain and satisfaction with their appearance. Photographs were taken under standardized conditions in accordance with a study photography manual at baseline and each follow-up visit. Outcomes were assessed by three, independent blinded reviewers using photographs before treatment and 3 months, 6 months, and one year post-treatment to verify the effectiveness of the procedure. The one year results demonstrate safety and durability through one year.

No Unanticipated Adverse Device Effects (UADE), related Serious Adverse Events (SAE) nor severe adverse events occurred in the study. The primary safety endpoint for the study was achieved with no device related SAEs at 30 days. Any undesirable medical occurrence was considered an adverse event. There were three adverse device effects (ADEs) that occurred in two participants: 1) an extended incision to facilitate removal of device in Hook Position, 2) a skin laceration (~1mm), and 3) a small scar from the skin laceration. The types and rates of the observed events are typical of this mechanism of action and were generally mild, transient, and only four events involved interventions to resolve: (1) aeration of ~2x1cm discreet subcutaneous mass (2) seroma requiring aspiration (3) hematoma requiring aspiration, and (4) stitching an extended device entry incision. The most common AEs were ecchymosis (86.8%), tenderness (51.5%), pain (38.2%), induration (36.8%) and numbness (17.6%). Ecchymosis had a median duration of 27 days, tenderness a median duration of 21 days, induration a median of 172 days, and numbness a median of 58 days. Many participants (83.8%, 57/68) experienced tenderness or pain within the first 24 hours. Some participants (13/68, 19.1%) could return to normal activities the day of the procedure, and most (50/68, 73.5%) within a week. Of the most common adverse events reported, induration had the longest mean duration. Generally, the induration was described as small areas of firmness, not visible or painful, and not associated with the incision site. A small proportion of adverse events (6.0%) were ongoing at study exit (one year) and included induration, numbness, skin hyperpigmentation, skin dysaesthesia, and skin indentation (also described as a depression or other irregularity). The skin indentations (2/68, 2.9%) presented at 3 months and 6 months, respectively. No medical intervention was required.

In the clinical study, effectiveness was evaluated with an improvement assessment by independent physician evaluation of participant photographs. Participants were overall satisfied with their cellulite procedure results. The participant photo evaluation was conducted by an independent firm in accordance

with the study protocol whereby the evaluators were disclosed nothing about the sponsor, the investigational device, or the clinical investigators. A total of three independent physician evaluators were selected, individually trained, and monitored throughout the evaluation. In the evaluation, blinded before (baseline) and after photographs were provided side by side in randomized orientation (L-R) and the physician evaluators were asked to identify the baseline and after photographs and rate the overall improvement according to a Global Aesthetic Improvement Scale GAIS and the Cellulite Severity Scale (CSS). All reliability and repeatability measures were met at 3 months and validated the methodology.

The overall study success criterion was achievement of a safe and clinically significant improvement in the appearance of cellulite in the treated subjects. 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 the independent, blinded physician evaluators comparing baseline and 3-month photos. The primary effectiveness endpoint was achieved. The CSS evaluations at 6 and 12 months demonstrated durability through one year.

In conclusion, the study primary endpoints were achieved, and results were sustained at one year. The in vivo performance data collected in the pivotal study demonstrates that Avéli is both safe and effective for treating cellulite in the buttock and thigh locations.

Conclusion

This Traditional 510(k) Premarket Notification is to extend treatment benefits in the indications for use through one year of observation. The updated indications for use do not pose any new questions of safety or efficacy. Clinical study data demonstrates treatment benefits through one year of observation. Therefore, Avéli device is substantially equivalent to the predicate device in terms of safety and effectiveness for long-term reduction in the appearance of cellulite in the buttocks and thigh areas of adult females.