August 18, 2023

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

Re: K232153
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, GDI, FTD
Dated: July 19, 2023
Received: July 19, 2023

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.08.18 10:21:15 -04'00'

Mark Trumbore, 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)*
K232153

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. Avéli is also indicated for soft tissue dissection during general and plastic surgical procedures.

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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1 Contact Details

Applicant Name: Revelle Aesthetics, Inc.

Applicant Address: 2570 W El Camino Real Suite 310
Mountain View CA 94040 United States

Applicant Contact Telephone: 650-336-5985

Applicant Contact: Ms. Melissa Viotti

Applicant Contact Email: mviotti@revelleax.com

Date Summary Prepared: 08/17/2023

2 Device Name

Device Trade Name: Avéli

Common Name: Powered surgical instrument for improvement in the appearance of cellulite

Classification Name: Powered surgical instrument for improvement in the appearance of cellulite

Regulation Number: 878.4790

Product Code: OUP

Regulation Number: 878.4800

Product Code: GDI

Regulation Number: 878.4580

Product Code: FTD

3 Legally Market Predicate Devices

Predicate #	Predicate Trade Name	Product Code
K221336	Avéli	OUP
K111020	AtriCure Dissector	GDI, FTD

4 Device Description Summary

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. Avéli also dissects soft tissue in general and plastic surgical procedures. 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 captures the nearby septa or other soft tissue resulting in tugging. The user feels the resistance, confirming that septa under a cellulite depression or other treatment area 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 soft tissue. The user then retracts the Blade and the Blocker into the device, allowing removal without further tissue engagement. The user can verify all appropriate soft tissue has been released by passing through the area again with the Hook. The step is repeated for each visible cellulite depression or other surgical area.

5 Intended Use / 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 also indicated for soft tissue dissection during general and plastic surgical procedures.

6 Indications for Use Comparison

The device modifications do not constitute a new intended use compared to the legally marketed predicate devices. The subject device has the same principles of operation and same technological characteristics as the previously cleared predicate Avéli. Revelle proposes to add an indication to Avéli for soft tissue dissection in general and plastic surgical procedures. Revelle has identified an additional predicate

device, the AtriCure Dissector, that has similar indications for use and similar technological characteristics as the modified device. The AtriCure Dissector is indicated for soft tissue dissection during general, ENT, thoracic, urological and gynecological surgical procedures. The modified Avéli device is not intended for a different use compared to the legally marketed AtriCure Dissector predicate device for the same use (soft tissue dissection), and the indicated surgical procedures (general/plastic surgery) are more limited than the predicate device's (general, ENT, thoracic, urological and gynecological). In other words, the modified Avéli device labeling (soft tissue dissection in general and plastic surgical procedures) does not constitute a new intended use compared to the cleared AtriCure Dissector device.

7 Technological Comparison

The modified Avéli device has the same technological characteristics as the cleared Avéli device. Like Avéli, the AtriCure Dissector has a battery-powered light source which is used to navigate soft tissue for identification and isolation of anatomic structures. Both devices would be used by qualified health care professionals. Both devices operate under the same fundamental scientific technology (nonpowered tissue dissection and battery powered illumination). Both devices provide controlled dissection with a mechanical articulating feature and have a stainless steel dissecting component. The AtriCure Dissector, like Avéli, is single use only and is EO sterilized.

8 Non-Clinical and/or Clinical Tests Summary & Conclusions.

The following performance testing was completed or reviewed to verify or validate 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
4) 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)
5) Biocompatibility Testing (ISO 10993-1:2018)
6) Sterilization Validation (ISO 11135-1:2014, ISO 14161:2009)
7) Packaging Validation (ISO 11607-1:2020+A11:2022)

9 Conclusion

This 510(k) Premarket Notification is to expand indications for use to include soft tissue dissection during general and plastic surgical procedures. The updated indications for use do not pose any new questions of safety or efficacy. Performance test data demonstrates sufficient performance for soft tissue dissection. Therefore, Avéli device is substantially equivalent to the predicate device in terms of safety and effectiveness for requested intended use.