April 7, 2023

Aroa Biosurgery Ltd.
Tina O'brien
Director, Regulatory Affairs
2 Kingsford Smith Place
Airport Oaks, Auckland 2022
New Zealand

Re: K223373
Trade/Device Name: Enivo™
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: BTA,
Dated: March 10, 2023
Received: March 10, 2023

Dear Tina O'brien:

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: 2023.04.07 13:28:45 -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.

Submission Number *(if known)*

K223373

Device Name

Enivo™

Indications for Use *(Describe)*

Enivo™ is indicated for use to remove surgical and bodily fluids from a closed wound for hematoma and seroma prophylaxis following plastic surgery or other general surgeries where large flaps are formed.

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.

510(k) #: K223373

510(k) Summary

Prepared on: 2023-04-07

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Aroa Biosurgery Ltd.
Applicant Address	2 Kingsford Smith Place Airport Oaks AKL 2022 New Zealand
Applicant Contact Telephone	+64 098693035
Applicant Contact	Ms. Tina O'Brien
Applicant Contact Email	tina.obrien@aroabio.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Enivo™
Common Name	Powered suction pump
Classification Name	Pump, Portable, Aspiration (Manual Or Powered)
Regulation Number	878.4780
Product Code	BTA

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K222856	SOMAVAC Device	BTA

Device Description Summary

21 CFR 807.92(a)(4)

Enivo™ is a surgical drainage system intended for the removal of surgical and bodily fluids from a closed wound. The system can be used in both home and healthcare environments.

The system includes two primary components:
• A vacuum device unit that includes a single-use, portable, and battery-powered vacuum device that provides continuous operation for up to 30 days and a disposable exudate reservoir.
• a removable silicone drainage catheter

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Enivo™ is indicated for use to remove surgical and bodily fluids from a closed wound for hematoma and seroma prophylaxis following plastic surgery or other general surgeries where large flaps are formed.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Enivo™ shares the same intended use and indications as the predicate.

Technological Comparison

21 CFR 807.92(a)(6)

The predicate device uses the same fundamental technology and use configuration as Enivo™ in that it is required to be connected to a Class I drainage catheter. The differences between Enivo™ and the predicate do not introduce a new intended use and do not raise new

issues of safety and effectiveness. Bench testing has demonstrated that no new types of risk to the patent have been introduced by these differences and that the device performs as intended.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The Enivo™ system complies with voluntary standards for electrical safety, electromagnetic compatibility, and sterile drainage catheters. The following data was provided in support of the substantial equivalence determination:

- Software verification and validation testing
- Electrical safety and electromagnetic compatibility testing were conducted per IEC 60601 1:2005+AMD1:2012+AMD2:2020 with US deviations per AAMI ES60601-1:2005+AMD1:2012+AMD2:2021, IEC 60601-1-2:2014+AMD1:2020, IEC 60601-1-8:2006+AMD1:2012 +AMD2:2020, IEC 60601-1-11:2015+AMD1:2020, and AIM 7351731:2017
- Biocompatibility evaluated as per ISO 10993-1:2018
- Vacuum pressure and flow rate performance testing
- Battery life testing
- Endurance runtime via simulated use testing
- Performance and safety assessed according to the applicable parts of ISO 20697:2018
- Package integrity assessed as per ASTM F1929:2015, ASTM F2096:2019, and ISO 11607-1:2019
- Package seal strength assessed as per ASTM F88/F88M:2015
- Bacterial filtration efficiency assessed as per ASTM F2101:2019
- Sterilization confirmed by assessment in accordance with ISO 11135:2018
- Bacterial endotoxins assessed as per ANSI/AAMI ST72:2019
- Bioburden (pre-EO) assessed as per ISO 11737-1:2021
- Connection leak testing
- Quantification of connection/disconnection forces via uniaxial tensile and compression testing
- Mechanical strength assessed using uniaxial tensile and compression testing
- Alarm system assessed to perform as indicated in the instructions
- System performance assessed following simulated transportation testing as per ASTM D4169:2022

Clinical testing was not required to demonstrate the substantial equivalence of Enivo™ to the predicate device.

The intended use and indications for use of the subject device is substantially equivalent to the predicate device. The differences between Enivo™ and the predicate device do not introduce a new intended use and do not raise new issues of safety and effectiveness. Testing demonstrated that no adverse effects have been introduced by the technological differences and that Enivo™ performs as intended.

From the results of nonclinical testing described, Aroa Biosurgery concludes that Enivo™ is substantially equivalent to the legally marketed predicate device.