March 18, 2022

Ariste Medical LLC
℅ Brian Young
VP Regulatory and Clinical Affairs
Health Policy Associates Inc
690 Canton Street, Suite 302
Westwood, Massachusetts 02492

Re: K211132
Trade/Device Name: ARISTE AB Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: May 5, 2021
Received: May 7, 2021

Dear Brian Young:

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 and Part 809); 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 Deborah Fellhauer, RN, BSN
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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)*
K211132

Device Name
ARISTE AB Mesh

Indications for Use *(Describe)*
ARISTE AB Mesh is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue. Indications for use include the repair of hernias and/or body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome. The non-absorbable polymer coating on the mesh contains the antimicrobial agents, rifampin and minocycline to help provide protection from microbial colonization of the device during surgical implantation.

ARISTE AB Mesh is intended for single patient one-time use only.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SECTION 5: 510(K) SUMMARY for K211132

The following information is provided in accordance with 21 CFR 807.92, for the Premarket 510(k) Summary:

APPLICANT INFORMATION:

Company Name: ARISTE Medical, LLC

Company Address: 9950 S 300 W

Sandy UT 84070

SUBMITTED BY:

Company Name: ARISTE Medical LLC

Contact Name: Lisa K Jennings, PhD

Contact Address: 140 Collins St

Memphis, TN 38112

Phone: (901) 866-1700

E-mail: Ljennings@aristemedical.com

Date Prepared: 3/16/2022

DEVICE INFORMATION

Trade Name: ARISTE AB Mesh

Common Name: Surgical Mesh

Classification Name: Surgical Mesh

Regulation Number: 21 CRF 878.3300

Regulatory Class: II

Product Code: FTL

PREDICATE DEVICE INFORMATION:

The ARISTE AB Mesh claims substantial equivalence to PIVIT A/B ST AND PIVIT A/B ST-R Surgical Mesh cleared by FDA under K093524. XenMatrix AB Surgical Graft (K133223) and Prolene™ Mesh (K962530) are identified as reference devices.

DEVICE DESCRIPTION:

ARISTE AB Mesh is a non-resorbable sterile prosthesis designed to provide mechanical support for reconstruction of soft tissue deficiencies. The mesh is constructed of polypropylene fibers knitted together to form the mesh. The resulting structure is an implant which reinforces the tissue defect.

The mesh is coated with a thiolene polymer. The coating acts as a carrier for antibiotic agents rifampin and minocycline in equal concentrations of approximately 171µg/cm^2 to help provide protection from bacterial colonization of the device during surgical implantation. While the effectiveness of the rifampin and minocycline components has been evaluated via in vitro and in vivo testing, no clinical data nor clinical impact associated with this claimed reduction of bacterial colonization of the ARISTE AB mesh has been demonstrated.

INTENDED USE:

ARISTE AB Mesh is a non-resorbable polymeric surgical mesh intended to reinforce soft tissue where weakness exists.

INDICATIONS FOR USE:

ARISTE AB Mesh is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue. Indications for use include the repair of hernias and/or body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome. The non-resorbable polymer coating on the mesh contains the antimicrobial agents, rifampin and minocycline to help provide protection from microbial colonization of the device during surgical implantation.

ARISTE AB Mesh is intended for single patient one-time use only.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

ARISTE AB Mesh is similar in intended use and in technological characteristics and performance when compared to the cited predicate devices. ARISTE AB Mesh and the cited predicates are intended for use in the reconstruction and repair of soft tissue deficiencies where weakness exists such as hernia repair. In addition, these devices are similar in technological characteristics with regard to sterilization, packaging and labeling

Ariste AB Mesh is the same as the primary predicate PIVIT AB Mesh in the following respects: intended use; antimicrobial agents; mechanism of action; mesh material and method of construction; product handling; and method of implantation.

ARISTE AB Mesh differs from the primary predicate PIVIT AB Mesh in the following technological respects. Each technological difference is explained and supported with performance data.

- Antimicrobial amounts
    - The subject device contains equal amounts (171 µg/cm^2) of rifampin and minocycline whereas the predicate contains 86.11 µg/cm^2 of both rifampin and minocycline.
    - A 510(k) cleared device, Xenmatrix AB Surgical Graft, containing approximately the same antibiotic concentrations (180 µg/cm^2) is used as a reference device for purposes of demonstrating safety and effectiveness of the antibiotic concentration used.

- *In vitro* and *in vivo* performance and safety testing demonstrating of antimicrobial characteristics are provided.

- Polymer coating
  - The subject device utilizes a non-resorbable polymer coating as a substrate for the antibiotics whereas the PIVIT® AB uses a resorbable polyarylate.
  - Bench and animal Performance testing is provided.

- Physical characteristic
  - Mesh thickness (0.49 mm Ariste vs. 0.51-0.53 mm Prolene), weave characteristics (1.0 mm x 0.6 mm Ariste vs. 0.8-1.6 mm Prolene), and density (145 g/m^2 Ariste vs 79.5-108 g/m^2 Prolene) are similar to the predicate Prolene Mesh.
  - Bench and animal performance testing demonstrating the device's physical characteristics are provided.

PERFORMANCE TEST SUMMARY

The ARISTE AB Mesh underwent an extensive safety and performance testing program, including bench and animal testing, to demonstrate that the device meets the requirements as defined in user specifications, and performs as intended.

Packaging, Sterilization and Shelf Life Testing

The ARISTE AB Mesh packaging system consists of a double sterile barrier. The ARISTE AB Mesh is E-Beam sterilized to an SAL of 1 X 10^{-6} using validated methods pursuant to ISO/AAMI 11137. A combination of real time and accelerated age life testing supports 6 months expiry dating.

Biocompatibility testing

Biocompatibility testing was performed in accordance with ISO 10993-1:2018 and the *"Use of International Standard ISO-10993-1, 'Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a risk management process,"* (June 16, 2016) in accordance with the device's tissue contact category and duration of implantation (permanent).

Bench testing

In vitro testing was performed to assess the physical and performance characteristics of the ARISTE AB Mesh in accordance with FDA's *"Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh"* (March 2, 1999) as well as FDA's *"Premarket Notification [510(k)] Submissions for Medical Devices that Include Antimicrobial Agents" Antimicrobial Agents*" (July 19, 2007). The *in vitro* testing included the following physical and performance characterization evaluations:

a) Physical Characteristics:

i. Device Thickness

ii. Device Stiffness (ratio between strength and elongation)

b) Functional Characteristics:

i. Tensile strength (break strength)

ii. Elongation

iii. Burst Strength

iv. Suture Pullout Strength

v. Tear Resistance (single rip/tongue method)

Results indicated that the ARISTE AB Mesh meets or exceeds the minimum mechanical strength requirements.

Drug Elution and Antibiotic Effectiveness

Drug content and impurities analytical testing of the antibacterial agents rifampin and minocycline as well as *in vitro* testing were performed on the device: including elution/extraction, time kill studies, drug content and impurity, and drug release kinetics.

In *in vitro* studies, ARISTE AB Mesh demonstrated greater than 4 Logs of antibacterial activity against a panel of gram positive and gram-negative organisms including methicillin-resistant Staphylococcus aureus (MRSA), Staphylococcus epidermidis, Streptococcus pyogenes, Escherichia coli, Acinetobacter baumannii, and Enterobacter aerogenes for the first 2 days following implantation.

Animal Testing

The following GLP animal performance studies were performed to confirm safety and effectiveness in clinically relevant animal models.

- Tensile Strength Study in a Rabbit Abdominal Side Wall Defect Model "T-Peel Study"
- 7-Day Rabbit MRSA Inoculation Study
- 7-Day Rabbit MRSA and *E. Coli* Inoculation Study

In vivo animal inoculation confirmed clearance of clinically relevant organisms, Staphylococcus aureus (MRSA) and Escherichia coli for a period of 7 days.

CONCLUSION

The ARISTE AB Mesh is substantially equivalent to the predicate devices.