DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 29, 2017

Assut Europe S.p.A.
% Mr. Roger Gray
Donawa Lifescience Consulting Srl
Piazza Albania, 10
Rome, 00153 Italy

Re: K171039
Trade/Device Name: Assut Filbloc Permanent Sutures
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable polypropylene surgical suture
Regulatory Class: Class II
Product Code: GAW
Dated: July 18, 2017
Received: July 20, 2017

Dear Mr. Gray:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171039

Device Name
Assut FilBloc Permanent sutures

Indications for Use *(Describe)*
FilBloc Permanent sutures are intended for general soft tissue approximation, excluding closure of the epidermis, where use of a non-absorbable suture is appropriate.

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.

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510(k) Summary

Device Name:	Assut FilBloc Permanent Sutures
Type of 510(k) submission:	Abbreviated
Date of submission:	17 July 2017
Manufacturer:	Assut Europe SpA Zona Industriale 67062 Magliano dei Marsi (AQ) Italy
Phone: **Fax:**	+39-06-72677348 +39-06-72675380
FDA Registration Number:	9617547
510(k) Owner and Submitter:	Assut Europe SpA Via G.Gregoraci, 12 00173 Rome Italy
Owner/Operator Number:	9044488
510(k) Application Correspondent:	Mr Roger Gray VP Quality and Regulatory Donawa Lifescience Consulting Piazza Albania 10 00153 Rome Italy
Phone: **Fax:** **Email:**	+39 06 578 2665 +39 06 574 3786 rgray@donawa.com
FDA Product Code:	GAW
FDA Regulation Number:	21 CFR 878.5010
FDA Classification Name:	Nonabsorbable Polypropylene Surgical Suture
Classification Panel:	General and Plastic Surgery
Common Name:	Nonabsorbable Polypropylene Surgical Suture
FDA Classification:	Class II
Submission Type:	510(k)
Indication for Use:	FilBloc Permanent sutures are intended for general soft tissue approximation, excluding closure of the epidermis, where use of a non-absorbable suture is appropriate.
Predicate Device:	Quill Nonabsorbable Polypropylene barbed suture, K052373. From information on the FDA website, there is no indication that this device has been subject to a design-related recall.

Reference Device: Assut FilBloc Absorbable Polydioxanone Surgical Suture, K150553. This device has not been subject to a design-related recall.

Device Description:
The Assut FilBloc Permanent Suture range of devices comprises a variety of gauge sizes and lengths, supplied with or without stainless steel needles, which are also available in a variety of different sizes and shapes. The sutures may have a 'block' at one end, which allows surgeons to close wounds quickly and securely without tying knots or changing suturing techniques. The block is made from the same material as the suture, and is used to anchor the suture.

Assut FilBloc Permanent Sutures contact the patient and remain attached to the patient at the point suturing and may remain in place for significant periods.

The sutures with needles do not need to be used with any other devices, but the needleless sutures need to be used together with legally available separate needles.

Technological Characteristics:
The sutures are manufactured in polypropylene monofilament thread, white natural (undyed) or dyed blue colour (phthalocyanine copper - C.I. 74160; 21 CFR§ 74.3045). The suture thread can be smooth or can have unidirectional or bidirectional barbs along the axis of the monofilament surface, either convergent or divergent.

The chemical formula of polypropylene is -(CH(CH3)-CH2)n. The chemical formula of the blue dye is C32H16CuN8. The suture content of the blue dye is below 0.5 wt%.

Assut FilBloc Permanent Sutures are available sterile (ethylene oxide, with SAL 10^{-6}) for single use in a wide range of lengths and in sizes from USP 2 to 4/0, (sizes USP 4/0, USP 3/0, USP 2/0, USP 0, USP 1, USP 2), with or without needles (single or double), with or without single-end blocks, and with or without barbs. The barbs can be unidirectional or bidirectional, and if bidirectional, the barbs can be opposing each other or not, at the purchaser's choice.

Performance Data:
Physical testing was performed to establish compliance with USP 29, including <861> suture diameter, <871> suture attachment, <881> tensile strength. Tests were also undertaken to establish sterility, shelf life and packaging integrity.

Biocompatibility:
In accordance with the recommendations of ISO 10993-1 and FDA guidance *'Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*', 16 June 2016, for devices described as implants in contact with tissue/bone for over 30 days, the following tests were carried out to establish the biocompatibility of the FilBloc Permanent Sutures:

- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Irritation or Intracutaneous Reactivity (ISO 10993-10)
- Acute Systemic Toxicity (ISO 10993-11)
- Subchronic Toxicity (ISO 10993-11)
- Genotoxicity (ISO 10993-3)
- Implantation (ISO 10993-6)
- Material Mediated Pyrogenicity

Bacterial endotoxin testing (LAL test) is carried out on every batch of sutures.

Substantial Equivalence:
The features and characteristics of predicate device and reference device selected for an evaluation of substantial equivalence with the Filloc Permanent Sutures are provided in Table 1, together with a comparison with the same features and charcteristics of the subject device.

Table 1: Predicate device comparison table

Item	Predicate Device	Subject device	Similarity
Device name	Quill Nonabsorbable Polypropylene Barbed Suture	FilBloc Permanent Sutures	N/A
Device Manufacturer	Angiotech, Reading PA, US	Assut Europe, Italy	N/A
510(k) Reference	K052373	Not yet assigned	N/A
FDA Product Code	GAW	GAW	Same
FDA Classification Name	Nonabsorbable polypropylene surgical suture	Nonabsorbable polypropylene surgical suture	Same
FDA Regulation Number	21 CFR 878.5010	21 CFR 878.5010	Same
Device description	Nonabsorbable polypropylene surgical suture in various thread sizes and needle shapes/sizes, with bi-directional thread barbs	Nonabsorbable polypropylene surgical suture in various thread sizes with or without unidirectional or bidirectional barbs, and with or without various needle shapes/sizes	Similar
Indications for Use / Intended use	Quill® Nonabsorbable Polypropylene Barbed Sutures are indicated for use in soft tissue approximation excluding closure of the epidermis.	FilBloc Permanent sutures are intended for general soft tissue approximation, excluding closure of the epidermis, where use of a non-absorbable suture is appropriate.	Equivalent to predicate. Very similar to reference device
Rx only?	Yes	Yes	Same
Monofilament?	Yes	Yes	Same
USP sizes	4/0 to 2	4/0 to 1	Different
Suture barbs	Bi-directional	None Bidirectional Unidirectional	Different from predicate but same as reference device
Locking block?	Not available	Optional	Different from predicate but same as reference device
Thread color	White Blue Copper	White Blue	Similar
Sterility	Sterile by EO, SAL 10^{-6}	Sterile by EO, SAL 10^{-6}	Same
Single use?	Yes	Yes	Same
Complies with applicable USP monographs?	Yes	Yes	Same

Table 1: Predicate device comparison table			
Item	**Predicate Device**	**Subject device**	**Similarity**
Needles attached?	Yes	Yes Also available without needles	Different from predicate but same as reference device
Needle shapes	1/2 circle 3/8 circle	1/2 circle 3/8 circle 5/8 circle “ski” needle Straight	Different from predicate but same as reference device
Needle cross-section	Unknown	Cylindrical Triangular Trapezoidal	Same as reference device
Needle point	Taper Diamond	Cylindrical Triangular Diamond (Taper-cut) Blunt point Spatula	Different from predicate but same as reference device
Needle eye	Unknown	Open Closed	Same as reference device
Needle materials	Surgical stainless steel: AISI 470	Surgical stainless steel: AISI 470 AISI 455 AISI 301 AISI 302 AISI 304 AISI 304L AISI 316 AISI 320 AISI 321 Cobalt chromium	Similar, same as reference device
Needle coating	Siliconized	Siliconized	Same
Biocompatibility	Biocompatible	Biocompatible	Same

The subject device and the predicate device have many identical or similar properties and features. In summary, the differencesare:

- **USP sizes available:** The subject device has one USP thread size less in its range.
- **Suture barb orientation:** The predicate device has bidirectional barbs on all versions in the range, whereas the subject device has options with or without barbs, and when barbs are included, these can be either bidirectional or unidirectional. The reference device has the same options of no barbs, bidirectional barbs and unidirectional barbs.
- **Locking block:** The predicate device does not offer a locking block option, whereas the subject device range does, which is the same as the reference device.
- **Needle sizes, shapes, points, etc:** The subject device includes a wider variety of needle sizes, shapes, points, etc, than the predicate device. The reference device has a similarly wide range of needle sizes, shapes, points, etc.

Conclusion:
Based on the information contained within this submission, it is concluded that the FilBloc Permanent Sutures are substantially equivalent to the identified predicate device already in interstate commerce within the USA.