DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 19, 2016

Assut Europe
Ms. Rhonda Alexander, M.S., M.P.A.
Registrar Corp.
144 Research Drive
Hampton, VA 23666

Re: K150553
Trade/Device Name: Filbloc
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable polydioxanone surgical suture
Regulatory Class: Class II
Product Code: NEW
Dated: April 12, 2016
Received: April 14, 2016

Dear Ms. Alexander:

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 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" (21CFR 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 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 yours,

Jennifer R. Stevenson -A

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)*
k150553

Device Name

Filbloc

Indications for Use *(Describe)*
Filbloc sutures are indicated for use in general soft tissue approximation where use of an 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

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510(k) Summary

I. SUBMITTER

Assut Europe SpA

Registered office:	Via G.Gregoraci, 12 00173 Roma - Italy
Manufacturing plant:	Zona Industriale 67062 Magliano dei Marsi (AQ) - Italy
Telephone:	+39-06-72677348
Fax Number:	+39-06-72675380
Contact Person:	Gloria Aggio
Date Prepared:	May 17, 2016

II. DEVICE

Name of Device:	Filbloc
Common or Usual Name:	Suture, Surgical, Absorbable, Polydioxanone
Classification Name:	Absorbable Polydioxanone Surgical Suture
Regulatory Class:	II
Product Code:	NEW
Regulation Number:	21 CFR 878.4840

III. PREDICATE DEVICE

Name:	Stratafix Symmetric PDS Plus Knotless Tissue Control
Manufacturer:	Ethicon, Inc.
K Number:	K141776
Name:	PDS II
Manufacturer:	Ethicon, Inc.
K Number:	N18331

This predicate has not been subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

Filbloc (polydioxanone) monofilament synthetic absorbable sutures are prepared from the polyester, poly(p-dioxanone). The empirical molecular formula of the polymer is:
$-(O\text{-}CH_2\text{-}CH_2\text{-}O\text{-}CH_2\text{-}CO)_n-$
Filbloc sutures are undyed or dyed with D&C Violet No. 2 (21CFR§ 74.3602).
The device is designed with unidirectional or bidirectional barbs, or with unidirectional barbs and final block in PDO. The barbs and the block design allow for tissue approximation, without need to tie surgical knot.

The device is available in various lengths and diameter sizes 2 through 4/0 with various needles attached at one end or to both ends.

V. INDICATIONS FOR USE

Filbloc sutures are indicated for general soft tissue approximation where use of an absorbable suture is appropriate.

VI. COMPARISON WITH THE PREDICATE DEVICE - SUMMARY

a. TECHNOLOGICAL CHARACTERISTICS

Parameter	**New device** **FilBloc smooth or barbed**	**Predicate device** **Stratafix Symmetric PDS Plus Knotless Tissue Control**
Chemical	Poly(p-dioxanone)	Poly(p-dioxanone)
USP sizes	4-0 to 2	3-0 to 1
Approx. Tensile Strength Residual at Time:	4 weeks 71.7% 8 weeks 16.5%	2 weeks ~75% 4 weeks ~65% 6 weeks ~ 55%
Absorption	~ 180-210 days post-implantation	~ 120-180 days post-implantation

b. INTENDED USE

	New device **Filbloc smooth or barbed**	**Predicate device** **Stratafix Symmetric PDS Plus Knotless Tissue Control**
Indication for use	Filbloc is indicated for use in soft tissue approximation where the use of absorbable suture is appropriate	Stratafix device is indicated for use in soft tissue approximation where the use of absorbable suture is appropriate
Precaution or controindication	It is therefore recommended that the surgeon will consider the possible use of non absorbable sutures for the closure of tissues which may undergo distension or stretching or requiring additional support. This suture kind may be inappropriate in elderly, malnourished or weakened patients or in patients suffering from conditions which may delay wound healing process	The Stratafix device is not to be used where prolonged (beyond six weeks) approximation of tissues under stress is required and is not to be used in conjunction with or for fixation of prosthetic devices that are nonabsorbable
Sterility	Ethylene Oxide gas	Ethylene Oxide gas

The new device, Filbloc, has similar technological characteristics as the predicate device; it conforms to the USP Monograph for absorbable surgical sutures, and has the same intended use as the predicate device.

Differences between Filbloc and the predicate device are:

1. Stratafix device is available in four USP sizes (USP 3-0, USP 2-0, USP 0, USP 1), whereas Filbloc device is available in six USP sizes (USP 4-0, USP 3-0, USP 2-0, USP 0, USP 1, USP 2)
2. Stratafix device is available only barbed, whereas Filbloc device is available barbed or smooth

VII. PERFORMANCE DATA

Physical testing was performed on poly(p-dioxanone) synthetic absorbable suture, to USP 29, including <861> suture diameter, <871> suture attachment, <881>tensile strength. Animal testing was performed for conformance to ISO 10993 for Biocompatibility.

Rabbit Implantation Tests in accordance with ISO 10993-6: 2007 were conducted with determinations of tensile strength.

Biocompatibility Testing

- Test for in vitro cytotoxicity (ISO 10993-5:2009)
- Irritation tests animal intracutaneous (intradermal) reactivity test (ISO 10993-10:2010)
- Skin sensitization tests – guinea pig maximization test (GPMT), extracted in sesame oil (ISO 10993-10:2010)
- Skin sensitization tests – guinea pig maximization test (GPMT), extracted in sterile solution of sodium chloride (ISO 10993-10:2010)
- Acute systemic toxicity (ISO 10993-11:2006)
- Rabbit subchronic systemic toxicity (ISO 10993-11:2006)
- Test of local effects after implantation (ISO 10993-6:2007)
- Genotoxicity Test Mouse Lymphoma Assay, extracted in Modified Eagle Medium without serum (ISO 10993-3:2003)
- Genotoxicity Test Mouse Lymphoma Assay, extracted in ethanol/water solution (ISO 10993-3:2003)

The subject device is considered an implant device with contact duration of over 30 days.

VIII. CONCLUSION

Filbloc in PDO sutures have the same intended use and same indication for use as the predicate devices “Stratafix”. The nonclinical and clinical data support a finding of substantial equivalence, since they demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device.