July 16, 2019

Purgo Biologics Inc.
% Seonghwan Song, RA Staff
E-607, 700, Pangyo-ro Bundang-gu
Seongnam-si
KR 13516 Gyeonggi-do

Re: K180992
Trade/Device Name: Biotex
Regulation Number: 21 CFR 878.5035
Regulation Name: Nonabsorbable Expanded Polytetrafluoroethylene Surgical Suture
Regulatory Class: Class II
Product Code: NBY
Dated: June 11, 2019
Received: June 13, 2019

Dear Seonghwan Song:

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,

Nina Mezu-Nwaba, PharmD., MPH., MSc, CAPT USPHS
Acting 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Biotex

Indications for Use *(Describe)*
Biotex Non-Absorbable PTFE Suture is indicated for use in dental soft tissue approximation and/or ligation. The device is not indicated for use in cardiovascular, ophthalmic surgery, microsurgery or peripheral neural tissue.
Biotex is provided sterile as a single use device and the duration of use or contact with the body is less than 30 days.

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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Section 5 – 510(k) Summary

I. SUBMITTER

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Date Prepared: 2018.04.05

II. DEVICE

Name of Device: Biotex
Common or Usual Name: PTFE Nonabsorbable Surgical Sutures
Classification Name: Nonabsorbable Expanded Polytetrafluoroethylene (ePTFE) Surgical Suture (21 CFR 878.5035)
Regulatory Class: Class II (special controls)
Product Code: NBY

III. PREDICATE DEVICE

Osteogenics Biomedical Inc. Cytoplast PTFE Suture, K072076
This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. SPECIAL CONTROLS

FDA Guidance "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA" was followed during the preparation of this submission.

V. DEVICE DESCRIPTION

Biotex Non-Absorbable PTFE Suture is comprised of a single-arm, non-absorbable monofilament suture and the stainless-steel surgical needle connected to the suture. It is composed of 100% high-density PTFE provided uncoated, undyed and sterile for one-time use only.

VI. INDICATIONS FOR USE

Biotex Non-Absorbable PTFE Suture is indicated for use in dental soft tissue approximation and/or ligation. The device is not indicated for use in cardiovascular, ophthalmic surgery, microsurgery or peripheral neural tissue.
Biotex is provided sterile as a single use device and the duration of use or contact with the body is less than 30 days.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Biotex Non-Absorbable PTFE Suture is substantially equivalent to the predicate device; Cytoplast PTFE suture, in which the basic features, raw materials and intended uses are the same. Biotex Non-Absorbable PTFE Sutures have been designed to meet the requirements for diameter, tensile strength, and needle adhesion as specified per USP. Any differences between the Biotex Non-Absorbable PTFE Suture and the predicate device are considered minor or insignificant. Therefore, it does not raise any questions concerning safety and effectiveness.

	Biotex Non-Absorbable PTFE Suture	Cytoplast PTFE Suture (K072076)
Product Code	NBY	Identical
Suture Characteristic	Non-absorbable expanded polytetrafluoroethylene surgical suture	Identical
Intended Use	Approximation and/or ligation of dental soft tissue	Identical
Technological Characteristic	Monofilament, uncoated, synthetic non-absorbable surgical suture	Identical
Material	polytetrafluoroethylene (PTFE)	Identical
Sizes	3-0, 4-0, 5-0 in 14" or 18" lengths	2-0, 3-0, 4-0 in 18" lengths
Sterilization	EO	Identical
Packaging	Device packaged in plastic case of racetrack design and inserted in Tyvek / Poly pouch	Device wound onto inner support card, within a Tyvek / Poly pouch
Contact Duration	Intended for use less than 30 days	Intended for use for 2 to 4 weeks

Purgo Dental Biologics Solution

VIII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Mechanical and Physical testing
Non-clinical laboratory performance testing was conducted to confirm that the Biotex Non-Absorbable PTFE Suture conforms to the USP monograph for non-absorbable sutures for diameter, tensile strength and needle attachment and also to show that it is substantially equivalent to the predicate device. This testing was performed in accordance with FDA's Class II Special Controls Guidance Document: Surgical Sutures, issued on June 3rd of 2003.

Biocompatibility testing
The biocompatibility evaluation for the Biotex Non-Absorbable PTFE Suture was conducted in accordance with the International Standard ISO 10993-1:2009 "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing Within a Risk Management Process" as recognized by FDA to further ensure substantial equivalence with the predicate device.
Assessment of the candidate device included the following tests:

- Cytotoxicity (ISO 10993-5)
- Sensitization Test (ISO 10993-10)
- Intracutaneous Reactivity (ISO 10993-10)
- Acute Systemic Toxicity (ISO 10993-11)
- Genotoxicity (ISO 10993-3)
- Implantation Test (ISO 10993-6)
- Pyrogen Testing
- EO Sterilization Residuals
- Shelf-Life

All of the acceptance criteria were met.

IX. CONCLUSIONS

Based on the information provided within this 510(k) submission, Purgo Biologics Inc. concludes that the Biotex Non-Absorbable PTFE Suture is substantially equivalent in safety and performance to the legally marketed predicate device listed according to the requirements of the Federal Food, Drug, and Cosmetic Act.

Completed by / Title:

Hana Jung / RA manager