January 28, 2019

Foosin Medical Supplies Inc., Ltd
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120 CN

Re: K183001
Trade/Device Name: WEGO-PGLA Rapid
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(Glycolide/L-Lactide) Surgical Suture
Regulatory Class: Class II
Product Code: GAM
Dated: September 28, 2018
Received: October 30, 2018

Dear Ms. Hong:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Cynthia Chang -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)*
K183001

Device Name
WEGO-PGLA RAPID

Indications for Use *(Describe)*
WEGO-PGLA RAPID sutures are intended for use in superficial soft tissue approximation of skin and mucosa where only short-term wound support is required. WEGO-PGLA RAPID is not intended for use in ligation, ophthalmic, cardiovascular or neurological procedures.

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.

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510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K183001

1. Date of Preparation: 01/24/2019

2. Sponsor Identification

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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: WEGO-PGLA RAPID
Common Name: Absorbable Synthetic Suture with or without Needle
Size: USP 6-0, USP 5-0, USP 4-0, USP 3-0, USP 2-0, USP 0, USP 1 and USP 2

Regulatory Information
Classification Name: Suture, Absorbable, Synthetic, Polyglycolic Acid
Classification: II
Product Code: GAM
Regulation Number: 21 CFR 878.4493
Review Panel: General & Plastic Surgery

Indications for Use:
WEGO-PGLA RAPID sutures are intended for use in superficial soft tissue approximation of skin and mucosa where only short-term wound support is required. WEGO-PGLA RAPID is not intended for use in ligation, ophthalmic, cardiovascular or neurological procedures.

Device Description
WEGO-PGLA RAPID sutures are synthetic, absorbable, braided, sterile surgical sutures composed of a copolymer made from 90% glycolide and 10% L-lactide. The empirical formula of the copolymer is $(C_2H_2O_2)_m(C_3H_4O_2)_n$. The characteristic rapid loss of strength is achieved by use of a polymer material with a lower molecular weight than regular WEGO-PGLA (Polyglactin 910) suture. WEGO-PGLA RAPID sutures are available undyed and dyed violet with D&C Violet No.2 (Colour Index number 60725).

WEGO-PGLA RAPID sutures are available in a range of gauge sizes and lengths, with and without stainless steel needles of varying types and sizes.

WEGO-PGLA RAPID sutures are uniformly coated with poly (glycolide-co-lactide) (30/70) and calcium stearate.

WEGO-PGLA RAPID sutures comply with the requirements of the European Pharmacopoeia for “Sutures, Sterile Synthetic Absorbable Braided” and the requirements of United States Pharmacopoeia for “Absorbable Surgical Suture” (except for an occasional slight oversize in diameter).

The Synthetic Absorbable Suture is provided EO sterilized as a single use device.

5. Identification of Predicate Device

510(k) Number: K944110
Product Name: VICRYL Rapide Suture
Manufacturer: ETHICON, INC

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- USP 40-NF 35:2017 <861> Sutures – Diameter;
- USP 40-NF 35:2017 <871> Sutures - Needle Attachment;
- USP 40-NF 35:2017 <881> Tensile Strength;
- ISO 10993-3:2014 Biological Evaluation of Medical Devices, Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity;
- ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity;
- ISO 10993-6:2007 Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation;
- ISO 10993-10: 2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization ;
- ISO 10993-11:2006 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity;
- USP 40-NF 35:2017 <85> Bacterial Endotoxins Test;
- ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials;
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration;
- ISO 10993-7:2008 Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals;
- USP 40-NF35:2017 <151> Pyrogen Test
- ASTM F756-13 Standard Practice For Assessment Of Hemolytic Properties Of Materials

The physical performance and stability of proposed device have been demonstrated by testing on samples before and after real-time-aging, to support the substantial equivalence between proposed device and the predicate, details are shown as follow:

Performance	Test Sample	Test Item	Result
Physical Performance	Device before aging	Diameter	Complies with USP <861>
		Tensile Strength	Complies with USP <881>
		Needle Attachment	Complies with USP <871>
Stability	Device after real-time-aging	Tensile Strength	Complies with USP <881>
		Needle Attachment	Complies with USP <871>

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Proposed Device and Predicated Device

Item	**Proposed Device**	**Predicate Device K944110**
Product Code	GAM	GAM
Regulation Number	21 CFR 878.4493	21 CFR 878.4493
Class	II	II
Intended Use	WEGO-PGLA RAPID sutures are intended for use in superficial soft tissue approximation of skin and mucosa where only short-term wound support is required. WEGO-PGLA RAPID is not intended for use in ligation, ophthalmic, cardiovascular or neurological procedures.	The Vicryl Rapide Suture is indicated only for use in superficial soft tissue approximation of skin and mucosa where only short-term wound support (7-10 days) is required. Vicryl Rapide Suture is not intended for use in ligation, ophthalmic, cardiovascular or neurological procedures.
Configuration	Suture and Needle	Suture and Needle
Sterility	EO Sterilized	EO Sterilized
Single Use	Yes	Yes
Based Material	90% glycolide and 10% L-lactide.(PGLA)	90% glycolide and 10% L-lactide (PGLA)
Coating Material	poly(glycolide-co-lactide) (30/70) and calcium stearate .	Polycaprolactone and calcium stearate
Color	Dyed and undyed	Dyed and undyed
Color Additive Material	D&C Violet No.2	D&C violet No. 2

Absorbable / Non-absorbable	Absorbable	Absorbable
Braided / Monofilament	Braided	Braided
Suture Size	USP 6-0, USP 5-0, USP 4-0, USP 3-0, USP 2-0, USP 0, USP 1 and USP 2	Unknown
Length of Suture	25cm, 30cm, 45cm, 50cm, 60cm, 70cm, 75cm and 90cm	Unknown
Absorption Time	42~56days	42 days

The based material of proposed device is PGLA, which is similar with that of predicate device. And the performance and biocompatibility of proposed device has been demonstrated by various tests. The specifications of predicate devices are not known, however, the proposed device has been demonstrated to comply the requirements listed in USP Monograph of Absorbable Surgical Suture. The absorption time of proposed device is similar with predicate devices. The comparison implantation and absorption tests have been conducted to confirm the absorption time of the proposed device.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate devices.