October 20, 2020

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

Re: K201139
Trade/Device Name: WEGO-PDO Barbed Suture
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable Polydioxanone Surgical Suture
Regulatory Class: Class II
Product Code: NEW
Dated: September 15, 2020
Received: September 17, 2020

Dear Diana 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/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,

Cindy Chowdhury, Ph.D., M.B.A.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201139

Device Name
WEGO-PDO Barbed Suture

Indications for Use *(Describe)*
WEGO-PDO Barbed Suture is indicated for 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K201139

1. Date of Preparation: 10/9/2020

2. Sponsor Identification

Foosin Medical Supplies Inc., Ltd.
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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: WEGO-PDO Barbed Suture
Common Name: Absorbable Polydioxanone Surgical Suture
Size: USP 5-0, USP 4-0, USP 3-0, USP 2-0, USP 0, USP 1, USP 2

Regulatory Information
Classification Name: Absorbable polydioxanone surgical suture
Classification: II

Product Code: NEW
Regulation Number: CFR 878.4840
Review Panel: General & Plastic Surgery

Indications for Use:

WEGO-PDO Barbed Suture is indicated for soft tissue approximation where use of an absorbable suture is appropriate.

Device Description

The propose device, WEGO-PDO Barbed Suture, is monofilament, absorbable surgical suture. It is intended for soft tissue approximation where use of an absorbable suture is appropriate. The proposed devices are provided sterile and single use.

The proposed device is composed of suture with or without the needle.

The sutures with no needle attachments are only available with bi-directional barbs of 7*7 cm, 10*10 cm, 24*24 cm and 30*30 cm, the diameter of which are USP 2-0, USP0, USP1 and USP2.

The suture is made of poly(p-dioxanone). The suture is uncoated. The suture is available undyed and dyed. The suture is designed with small unidirectional and bidirectional barbs along the length of the device. Barbs allow for tissue approximation without the need to tie surgical knots.

The needle is made of stainless steel. The needles are available in six types: Taper, Reverse Cutting, Cutting, Taper Cutting, Blunt and Diamond. The Arc (Circle) of needle has 5/8 circle, 3/8 circle, 1/2 circle and Straight.

The proposed devices are provided in various combinations of suture length, barb, diameter, color (dyed or undyed), quantity of needle and needle types.

The proposed devices are sterilized by EO to achieve a SAL 10^{-6} and supplied in sterility maintenance package which could maintain the sterility of the device during the shelf life of 3 years.

5. Identification of Predicate Devices

Predicate Device 1
510(k) Number: K113744
Product Name: QuillTM PDO Knotless Tissue-Closure Device (Polydioxanone)
Manufacturer: Angiotech

Predicate Device 2
510(k) Number: K120827
Product Name: QuillTM PDO Knotless Tissue-Closure Device (Polydioxanone)

Manufacturer: Angiotech

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 42-NF 37:2019 Absorbable Surgical Suture
- USP 42-NF 37:2019 <85> Bacterial Endotoxins Limit;
- USP 42-NF 37:2019 <71> Sterility Test
- USP 42-NF 37:2019 <861> Sutures - Diameter
- USP 42-NF 37:2019 <871> Sutures - Needle Attachment
- USP 42-NF 37:2019 <881> Tensile Strength
- ISO 10993-3:2014 Biological Evaluation of Medical Devices, Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity;
- ISO 10993-4:2017 Biological evaluation of medical devices--Part 4: Selection of tests for interactions with blood
- ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity;
- ISO 10993-6:2016 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 10993-11:2017 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity;
- ISO 11135:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)]
- 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;
- ASTM F1140-13 Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages

The following stability testing was performed to support the proposed shelf life:
Performance and Package Integrity Test Report after Real time Aging (three years)

7. Clinical Test Conclusion

No clinical study is included in this submission.

K201139

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	**Proposed Device** WEGO-PDO Barbed Suture		**Predicate Device 1** K113744		**Predicate Device 2** K120827	**Remark**
Product Code	NEW		NEW		NEW	SE
Regulation Number	CFR 878.4840		CFR 878.4840		CFR 878.4840	SE
Class	II		II		II	SE
Indications for Use	WEGO-PDO Barbed Suture is indicated for soft tissue approximation where use of an absorbable suture is appropriate.		Quill™ PDO Knotless Tissue-Closure Device, comprised of Polydioxanone, is indicated for soft tissue approximation where use of an absorbable suture is appropriate.		Quill™ PDO Knotless Tissue-Closure Device, comprised of Polydioxanone, is indicated for soft tissue approximation where use of an absorbable suture is appropriate.	SE Analysis 1
Configuration	Suture and Needle		Suture and Needle		Suture and Needle	SE
Welded Loop	Manufacture Method	Ultrasonically welded	Manufacture Method	Ultrasonically welded	N/A	SE Analysis 2
	Purpose	a basic fixation loop and secure the fixation loop portion to robust tissue	Purpose	help to form a secondary variable loop and secure the device at the distal end		
	Length	10mm	Length	10mm		
Sterility	EO Sterilized		EO Sterilized		EO Sterilized	SE
SAL	1.0×10^{-6}		1.0×10^{-6}		1.0×10^{-6}	SE
Single Use	Yes		Yes		Yes	SE
。SUTURE						
Material	poly (p-dioxanone)		poly (p-dioxanone)		poly (p-dioxanone)	SE

K201139

Color	Undyed; dyed violet with D&C Violet No.2	dyed violet with D&C Violet No.2	dyed violet with D&C Violet No.2	SE Analysis 3
Absorbable / Non-absorbable	Absorbable	Absorbable	Absorbable	SE
Braided / Monofilament	Monofilament	Monofilament	Monofilament	SE
Type of barbs	Uni-directional, Bi-directional	Uni-directional,	Bi-directional	SE Analysis 4
Suture Size	USP 5-0, USP 4-0, USP 3-0, USP 2-0, USP 0, USP 1, USP 2	USP 0	USP 4-0, USP 3-0, USP 2-0, USP 0, USP 1, USP 2	SE Analysis 5
Suture Length	Models of uni-directional barb :15cm, 20 cm, 30 cm, 45 cm, 60 cm, 70 cm Models of bidirectional barb :7*7 cm, 10*10 cm, 14*14 cm, 18*18cm, 24*24 cm, 30*30 cm,36*36 cm, 40*40 cm, 45*45 cm	20 cm, 30 cm, 45 cm	7*7 cm, 10*10 cm, 14*14 cm, 16*16cm, 24*24 cm, 30*30m, 36*36 cm	SE Analysis 6
Diameter of Suture	The suture diameters of proposed device comply with the diameter requirement listed in USP <861> Diameter.	The suture diameters of proposed device complies with the diameter requirement listed in USP <861> Diameter.	The suture diameters of proposed device complies with the diameter requirement listed in USP <861> Diameter.	SE
Tensile Strength	The tensile strengths of proposed device comply with the tensile requirement listed in USP <881> Tensile Strength	The tensile strengths of proposed device complies with the tensile requirement listed in USP <881> Tensile Strength	The tensile strengths of proposed device complies with the tensile requirement listed in USP <881> Tensile Strength	SE

K201139

Needle Attachment	The bond between suture and needle of the applicant device meet the requirements defined in USP <871>.	The bond between suture and needle of the applicant device meet the requirements defined in USP <871>.	The bond between suture and needle of the applicant device meet the requirements defined in USP <871>.	SE
NEEDLE				
Cytotoxicity	No cytotoxicity.	The specific test items are unknown. However, the product should meet the requirements of ISO10993 series standards.	The specific test items are unknown. However, the product should meet the requirements of ISO10993 series standards.	SE Analysis 7
Max Sensitization	No skin sensitization.			
Intracutaneous Reactivity Test	No intracutaneous reactivity.			
SUTURE				
Cytotoxicity	No cytotoxicity.	The specific test items are unknown. However, the product should meet the requirements of ISO10993 series standards.	The specific test items are unknown. However, the product should meet the requirements of ISO10993 series standards.	SE Analysis 8
Max Sensitization	No skin sensitization.			
Intracutaneous Reactivity Test	No intracutaneous reactivity.			
Acute Systemic Toxicity Test	No systemic toxicity.			
Genotoxicity	No genotoxicity.			
Pyrogenicity	No potential febrile reaction.			
Muscle Implantation Study	No reaction to the tissue.			
Sub chronic Toxicity Study	No systemic toxicity.			
Hemolysis Test (Direct Contact)	No Hemolysis			
Hemolysis Test (Indirect Contact)	No Hemolysis			

K201139

SE Analysis 1 – Indications for Use

The indications for use of Predicate device 1 and Predicate device 2 includes the material (Polydioxanone) of suture. Although the indications for use of Proposed Device does not include the material of suture, the suture's material of Proposed Device is also Polydioxanone. Therefore, this item is considered to be substantially equivalent.

SE Analysis 2- Welded Loop

The manufacture method and length of proposed device's and predicate device's welded loop are same. Although the purpose of proposed device's and predicate device's welded loop is different, the proposed suture and predicate suture have the same material, technological characteristic, and intended use. Therefore, this item is considered to be substantially equivalent.

SE Analysis 3- Color

The suture of Predicate Device 1 and Predicate Device 2 is dyed. The suture of Proposed Device is available in undyed and dye. The color of Proposed Device and Predicate Device 1 and Predicate Device 2's suture is dyed with D&C Violet No. 2. The Proposed Device has more undyed suture than the Predicate Device 1 and Predicate Device 2. The test reports for the undyed suture of Proposed Device provided in this submission, including performance test, and stability demonstrates that the undyed Proposed Device complied with the requirements of USP Absorbable Surgical Suture. Therefore, this item is considered to be substantially equivalent.

SE Analysis 4- Type of barbs

The barbs of Proposed Device include uni-directional barb and bi-directional barbs. The uni-directional barb of Proposed Device is same with the barb of Predicate Device 1. The bi-directional barb of Proposed Device is same with the barb of Predicate Device 2. Therefore, this item is considered to be substantially equivalent.

SE Analysis 5- Suture Size

The suture sizes of Proposed Device and Predicate Device 2 are both identified in the currently recognized United States Pharmacopoeia; although the range of suture size of Proposed Device is more than that of the Predicate Device 2, the suture sizes of Proposed Device comply with the requirements listed in USP Monograph for Absorbable Surgical Suture. Additionally, the proposed suture and predicate suture have the same material, technological characteristic, and intended use. Therefore, this item is considered to be substantially equivalent.

SE Analysis 6- Suture Length

The requirements for suture length of Proposed Device and Predicate Device 1 and Predicate Device 2 are both identified in the currently recognized United States Pharmacopoeia; although we do not know the exact suture length of Predicate Device 1 and Predicate Device 2, the suture lengths of Proposed Device comply with the requirements listed in USP Monograph for Absorbable Surgical Suture. Additionally, the proposed suture and predicate suture have the same material, technological characteristic, and intended use. Therefore, this item is considered to be substantially equivalent.

SE Analysis 7- Needle Biocompatibility

K201139

The needle biocompatibility of Proposed Device and Predicate Device 1 and Predicate Device 2 are should meet the requirements of ISO10993 series standards; although we do not know the specific test items of Predicate Device 1 and Predicate Device 2, but the needle biocompatibility tests of Proposed Device have been performed in Cytotoxicity, Sensitization and Intracutaneous Reactivity Test. These studies can demonstrate the needle biocompatibility of Proposed Device. Therefore, this item is considered to be substantially equivalent.

SE Analysis 8- Suture Biocompatibility

The biocompatibility of Proposed Device and Predicate Device 1 and Predicate Device 2 meet the requirements of ISO10993 series standards; although we do not know the specific test items of Predicate Device 1 and Predicate Device 2, the biocompatibility tests of Proposed Device have been performed in Cytotoxicity, Max Sensitization, Intracutaneous Reactivity Test, Acute Systemic Toxicity Test, Genotoxicity, Pyrogenicity, Muscle Implantation Study, Sub chronic Toxicity Study, Hemolysis Test (Direct Contact) and Hemolysis Test (Indirect Contact). These studies can demonstrate the biocompatibility of Proposed Device. Therefore, this item is considered to be substantially equivalent.

9. Substantially Equivalent (SE) Conclusion

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