February 19, 2020

Foosin Medical Supplies Inc., Ltd.
℅ Diana Hong
General Manager
Med-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120 Cn

Re: K193209
Trade/Device Name: Wego-Stainless Steel
Regulation Number: 21 CFR 878.4495
Regulation Name: Stainless Steel Suture
Regulatory Class: Class II
Product Code: GAQ
Dated: October 26, 2019
Received: November 21, 2019

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/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,

For 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193209

Device Name
WEGO-STAINLESS STEEL

Indications for Use *(Describe)*
The WEGO-STAINLESS STEEL is indicated for use in abdominal wound closure, hernia repair, sternal closure and orthopaedic procedures including cerclage and tendon repair.

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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Tab #6 510(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: K193209

1. Date of Preparation: 26/10/2019

2. Sponsor Identification

Foosin Medical Supplies Inc., Ltd
No.20, Xingshan Road, Weihai Torch Hi-tech Science Park, Weihai, Shandong, 264210, China

Establishment Registration Number: 3006562124

Contact Person: Zhipeng Yang
Position: President of Technology
Tel: +86-631-5660576
Fax: +86-631-5621680
Email: Foosin-ce@163.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Christina Wu (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86(0)21 2281-5850
Fax: +1(0)360 925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: WEGO-STAINLESS STEEL
Common Name: Non-absorbable Surgical Suture with or without needle
Size: USP 7-0, USP 6-0, USP 5-0, USP 4-0, USP 3-0, USP 2-0, USP 7, USP 6, USP 5, USP 4, USP 3, USP 2, USP 1 and USP 0.

Regulatory Information

Classification Name: Stainless Steel Suture
Classification: II
Product Code: GAQ
Regulation Number: 21 CFR 878.4495
Review Panel: General & Plastic Surgery

Indications for Use:
The WEGO-STAINLESS STEEL is indicated for use in abdominal wound closure, hernia repair, sternal closure and orthopaedic procedures including cerclage and tendon repair.

Device Description
The proposed device, WEGO-STAINLESS STEEL, is monofilament, non-absorbable surgical suture composed of stainless steel. WEGO-STAINLESS STEEL is undyed and uncoated. The proposed device is composed of suture and needle. The sutures are available in a range of gauge sizes and lengths attached to stainless steel needles of varying types and sizes. WEGO-STAINLESS STEEL complies with the requirements of the United States Pharmacopoeia for Non-Absorbable Surgical Sutures.

5. Identification of Predicate Device

510(k) Number: K170767
Product Name: Surgical Stainless Steel Suture

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:

- 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
- ISO11137-1:2006 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ISO11137-2:2013 Sterilization of healthcare products-Radiation-Part2: Establishing the sterilization dose
- ASTM F88/F88M-15: Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F756-17:Standard Practice for Assessment of Hemolytic Properties of Materials
- ASTM F1929-15:Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- USP 41-NF 36:2018 Nonabsorbable Surgical Suture
- USP 41-NF 36:2018 <85> Bacterial Endotoxins Test
- USP 41-NF 36:2018 <151> Pyrogen Test (USP Rabbit Test)
- USP 41-NF 36:2018 <861> Sutures – Diameter
- USP 41-NF36:2018 <871> Sutures – Needle Attachment
- USP 41-NF 36:2018 <881> Tensile Strength

The following stability testing was performed to support the proposed shelf life:
Product performance test reports (one year, two years, three years, four years and five years)
Package integrity test reports (one year, two years, three years, four years and five years)

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

ITEM	Proposed Device WEGO-STAINLESS STEEL	Predicate Device Surgical Stainless Steel Suture K 170767	Remark
Product Code	GAQ	GAQ	SE
Regulation Number	21 CFR 878.4495	21 CFR 878.4495	SE
Class	II	II	SE
Intended Use	The WEGO-STAINLESS STEEL is indicated for use in abdominal wound closure, hernia repair, sternal closure and orthopaedic procedures including cerclage and tendon repair.	Surgical Stainless Steel Suture is indicated for use in abdominal wound closure, hernia repair, sternal closure and orthopaedic procedures including cerclage and tendon repair.	SE
Configuration	Suture and Needle	Suture and Needle	SE
Sterilization	Radiation sterilization	Radiation OR Ethylene Oxide	SE Analysis 1
SAL	1.0×10^{-6}	1.0×10^{-6}	SE
Single Use	Yes	Yes	SE
SUTURE			
Material	Stainless Steel	Stainless Steel	SE
Color	Undyed	Undyed	SE
Absorbable/ Non-absorbable	Non-absorbable	Non-absorbable	SE
Braided/ Monofilament	Monofilament	Monofilament	SE
Suture Size	WEGO-STAINLESS STEEL are available in sizes 7-0 through 7(metric sizes 0.5 -9.0) in a variety of lengths.	Surgical Stainless steel sutures are available in sizes 10-0 through 7(metric sizes 0.2 -9.0) in a variety of lengths.	SE Analysis 2
Suture Length	20cm, 23cm, 30cm, 35cm, 40cm, 45cm, 50cm, 60cm, 75cm,150cm	Unknown	SE Analysis 3
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 comply 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 comply with the tensile requirement listed in USP <881> Tensile Strength	SE
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>.	SE
NEEDLE			
Biocompatibility	Comply with ISO 10993	Comply with ISO 10993	SE
Biocompatibility			
Cytotoxicity	No cytotoxicity.	comply with ISO 10993	SE
Skin Sensitization	No skin sensitization.	comply with ISO 10993	
Intracutaneous Reactivity Test	No intracutaneous reacitivty.	comply with ISO 10993	
Acute Systemic Toxicity Test	No systemic toxicity.	comply with ISO 10993	
Genotoxicity: No genotoxicity.	comply with ISO 10993	Unknown	
Genotoxicity: No genotoxicity.	comply with ISO 10993	Unknown	
Pyrogenicity	No potential febrile reaction.	comply with ISO 10993	
Muscle Implantation Study	No reaction to the tissue.	comply with ISO 10993	
Subchronic Toxicity Study	No systemic toxicity.	comply with ISO 10993	
Hemolysis Test(Direct Contact)	No Hemolysis	comply with ISO 10993	
Hemolysis Test(Indirect Contact)	No Hemolysis	comply with ISO 10993	

SE Analysis 1 – Sterilization

The sterilization method of proposed device is radiation. The sterilization method of predicate device is radiation or Ethylene Oxide. The sterilization methods of predicate device include the radiation. Therefore, this item is considered to be substantially equivalent.

SE Analysis 2- Suture Size

The suture sizes of proposed device and predicate device are both identified in the currently recognized United States Pharmacopoeia; although the range of suture size of proposed device is smaller than that of the predicate device, the suture sizes of proposed device comply with the requirements listed in USP Nonabsorbable 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 3- Suture Length

The requirements for suture length of proposed device and predicate device are both identified in the currently recognized United States Pharmacopoeia; although we do not know the exact suture length of predicate device, the suture lengths of proposed device comply with the requirements listed in USP Nonabsorbable 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.

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.