DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 31, 2017

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

Re: K170842
Trade/Device Name: WEGO-PTFE
Regulation Number: 21 CFR 878.5035
Regulation Name: Nonabsorbable Expanded Polytetrafluoroethylene Surgical Suture
Regulatory Class: Class II
Product Code: NBY
Dated: June 15, 2017
Received: June 20, 2017

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. 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" (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 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,

David Krause -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)*
K170842

Device Name
WEGO-PTFE

Indications for Use *(Describe)*
WEGO-PTFE is indicated for use in all types of soft tissue approximation and/or ligation, including cardiovascular, dental and general surgeries. The device is not indicated for use in ophthalmic surgery, microsurgery and peripheral neural tissue.

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 #7 510(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: K170842

1. Date of Preparation: 7/23/2017

2. Sponsor Identification

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

Ms. Diana Hong (Primary Contact Person)
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4. Identification of Proposed Device

Trade Name: WEGO-PTFE
Common Name: Non-Absorbable Surgical Suture
Size: USP 6-0, USP 5-0, USP 4-0, USP 3-0 and USP 2-0

Regulatory Information
Classification Name: Nonabsorbable Expanded Polytetraflouroethylene Surgical Suture
Classification: II
Product Code: NBY
Regulation Number: CFR 878.5035
Review Panel: General & Plastic Surgery

Indications for Use:

WEGO-PTFE is indicated for use in all types of soft tissue approximation and/or ligation, including cardiovascular, dental and general surgeries. The device is not indicated for use in ophthalmic surgery, microsurgery and peripheral neural tissue.

Device Description

The proposed device, WEGO-PTFE, is monofilament, synthetic, non-absorbable surgical suture composed of 100% polytetrafluoroethylene without any additives. The molecular formula is $(C_2F_4)n$. WEGO-PTFE is undyed and uncoated.

The proposed device is composed of suture and needle.

WEGO-PTFE is indicated for use in all types of soft tissue approximation and/or ligation, including cardiovascular, dental and general surgeries. The device is not indicated for use in ophthalmic surgery, microsurgery and peripheral neural tissue.

The sutures are available in a range of gauge sizes and lengths attached to stainless steel needles of varying types and sizes.

WEGO-PTFE complies with the requirements of the European Pharmacopoeia for Sterile Non-Absorbable Strands and the requirements of the United States Pharmacopoeia for Non-Absorbable Surgical Sutures.

5. Identification of Predicate Device

510(k) Number: K072076
Product Name: Cytoplast PTFE Suture
Manufacturer: Osteogenics Biomedical, 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 39-NF 34:2016 Nonabsorbable Surgical Suture;
- USP 39-NF 34:2016 <861> Sutures – Diameter;
- USP 39-NF 34:2016 <871> Sutures - Needle Attachment;
- USP 39-NF 34:2016 <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 <85> Bacterial Endotoxins Limit;
- ASTM F88/F88M-09 Standard Test Method for Seal Strength of Flexible Barrier Materials;
- ASTM F1140/F1140M-13, Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages;
- ASTM F1929-12 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;
- ISO 11737-2:2009, Sterilization of medical devices-Microbiological methods-Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

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

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 (K072076)

Item	**Proposed Device WEGO-PTFE**	**Predicate Device Cytoplast PTFE Suture K072076**
Product Code	NBY	NBY
Regulation Number	CFR 878.5035	CFR 878.5035
Class	II	II
Intended Use	WEGO-PTFE is indicated for use in all types of soft tissue approximation and/or ligation, including cardiovascular, dental and general surgeries. The device is not indicated for use in ophthalmic surgery, microsurgery and peripheral neural tissue.	The Cytoplast PTFE suture is indicated for use in all types of soft tissue approximation and/or ligation, including cardiovascular, dental and general surgeries, as well as repair of the dura mater. The device is not indicated for use in ophthalmic surgery, microsurgery and peripheral neural tissue.
Material	Polytetrafluoroethylene	Polytetrafluoroethylene
Color	Undyed	Undyed
Absorbable / Non-absorbable	Non-absorbable	Non-absorbable
Braided / Monofilament	Monofilament	Monofilament
Sterility	EO Sterilized	EO Sterilized
Suture Size	USP 6-0, USP 5-0, USP 4-0, USP 3-0, USP 2-0	USP 4-0, USP 3-0, USP 2-0
Single Use	Yes	Yes
Performance	Comply with: USP 39 <861> USP 39 <871> USP 39 <881>	Comply with: USP 30 <861> USP 30 <871> USP 30 <881>
Biocompatibility	Conforms to the requirements of ISO 10993 series Standards	Conforms to the requirements of ISO 10993 series Standards

9. Substantially Equivalent (SE) Conclusion

Based on the comparison, the intended use, characteristic, materials, sterility of proposed device is determined to be Substantially Equivalent (SE) to the predicate device.

In addition, the results of performance tests performed on the proposed device can also demonstrate the proposed device is complied with FDA recognized standards, which the predicate device was also complied with. The results of biocompatibility studies performed on the proposed device demonstrate that the patient materials used in proposed device are biocompatible.

Based on the comparison above, the proposed device, WEGO-PTFE, is determined to be Substantially Equivalent (SE) to the predicate device.