DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 14, 2014

Foosin Medical Supplies Incorporated, LTD
Ms. Diana Hong
MID-LINK Consulting Company, LTD
P.O. Box 120-119
200120 Shanghai
China

Re: K142810
Trade/Device Name: WEGO-PGCL Absorbable Surgical Monofilament Suture
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly (glycolide/l-lactide) surgical suture
Regulatory Class: Class II
Product Code: GAM
Dated: October 27, 2014
Received: October 30, 2014

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" (21CFR 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 yours,

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)*

K142810

Device Name

WEGO-PGCL Absorbable Surgical Monofilament Suture

Proposed Models: 6-0, 5-0, 4-0, 2-0, 0 and 1

Indications for Use *(Describe)*

The WEGO-PGCL Absorbable Surgical Monofilament Suture is indicated for use in general soft tissue approximation and/or ligation, but not for use in 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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

# Section 3 510(k) Summary

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

The assigned 510(k) Number: _____

1. Date the summary was prepared: 09/01/2014

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: Suxia Zhao
   Position: Deputy Chief Engineer
   Tel: +86-631-5621632
   Fax: +86-631-5620555
   Email: zsx9001@sina.com

3. Submission Correspondent

   Ms. Diana Hong& Mr. Lee Fu
   Mid-Link Consulting Co., Ltd
   P.O. Box 120-119
   Shanghai, 200120, China
   Tel: +86-21-22815850
   Fax: 240-238-7587
   Email: info@mid-link.net

4. Proposed Device Identification

Proposed Device Name: WEGO-PGCL Absorbable Surgical Monofilament Suture
Common Device Name: PGCL Synthetic Absorbable Suture
Proposed Models: 6-0, 5-0, 4-0, 2-0, 0 and 1

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

Intended Use Statement:
The WEGO-PGCL Absorbable Surgical Monofilament Suture is indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological procedures.

5. Predicate Device Identification

510(k) Number: K130737
Product Name: WEGO-PGCL Absorbable Surgical Monofilament Suture
Manufacturer: Foosin Medical Supplies Inc., Ltd

6. Device Description

The WEGO-PGCL Absorbable Surgical Monofilament Suture is a monofilament, synthetic absorbable suture indicated for use in soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological surgery.

The Synthetic Absorbable Suture is composed of poly (glycolide-co-caprolactone) (PGCL); and it is available dyed and undyed (natural). The D&C violet No. 2 (Colour Index Number 60725) is the used colorant for dyed suture.

The proposed suture is available in 6-0, 5-0, 4-0, 2-0, 0 and 1, which are the sizes identified in the currently recognized United States Pharmacopoeia.

The performance of this absorbable sutures complies with United States Pharmacopeia (U.S.P.) monograph requirements for Absorbable Surgical Suture, USP 35<861>, USP 35<871> and USP35 <881>.

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

7. 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 35 <861> SUTURES - DIAMETER
USP 35 <871> SUTURES – NEEDLE ATTACHMENT
USP 35 <881> TENSILE STRENGTH
USP MONOGRAPH OF ABSORBABLE SURGICAL SUTURE

Additionally, the residual strength and absorption rate studies were demonstrated and the sutures were evaluated in accordance with the requirements outlined in FDA's Class II Special Controls Guidance Document: Surgical Sutures

8. Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

Table 3-1 Comparison of Technology Characteristics

| Item | Proposed Device(s) | Predicate Device K130737 |
|---|---|---|
| Product Code | GAM | GAM |
| Regulation Number | 21 CFR 878.4493 | 21 CFR 878.4493 |
| Class | II | II |
| Intended Use | The WEGO-PGCL Absorbable Surgical Monofilament Sutureis indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological procedures. | The WEGO-PGCL Absorbable Surgical Monofilament Sutureis indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological procedures. |
| Configuration | PGCL Suture and Needle | PGCL Suture and Needle |
| Sterile | Yes | Yes |
| Single Use | Yes | Yes |
| Suture | | |
| Material | glycolide-co-caprolactone (PGCL) | SAME |
| Color | Dyed suture (Violet), Undyed Suture | SAME |

| | | |
|---|---|---|
| Absorbable/Nonabsorbable | Absorbable | SAME |
| Multifilament/Monofilament | Monofilament | SAME |
| Suture Size | The proposed device is available in6-0, 5-0, 4-0, 2-0, 0 and 1, which are the sizes identified in the currently recognized United States Pharmacopoeia. | The proposed device only has 3-0 model, which is the size identified in the currently recognized United States Pharmacopoeia. |
| Length of Suture | 30cm, 45cm, 60cm, 75cm, 90cm, 100cm, 120cm, 150cm, 180cm, 200cm, 250cm, 280cm, 300cm, 320cm, 360cm and 390cm | SAME |
| Diameter of Suture | The suture diameters of proposed device comply with the diameter requirement listed in USP 35 <861> Diameter. | SAME |
| Tensile strength | The tensile strengths of proposed device comply with the tensile requirement listed in USP 35 <881> Tensile Strength | SAME |
| Needle Attachment | The bond between suture and needle of the applicant device meet the requirements defined in USP 35 <871>. | SAME |
| Needle | | |
| Material | Stainless Steel | SAME |
| Needle type | Taper, Cutting, Blunt | SAME |
| Biocompatibility | Comply with ISO 10993-3, ISO 10093-5, ISO 10993-6, ISO 10993-10, ISO 10993-11 Standard | SAME |

The proposed device, WEGO-PGCL Absorbable Surgical Monofilament Suture, is determined to be Substantially Equivalent (SE) to the predicate device, WEGO-PGCL Absorbable Surgical Monofilament Suture (K130737), in respect of safety and effectiveness.