JAN 14 2014

Exhibit# 8 Revised 510(k) Summary

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

The assigned 510(k) Number: K130735

1. Date of Submission: Jan 07, 2014

2. Sponsor

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 237-023, Shanghai, 200237, China
Tel: +86-21-22815850
Fax: 240-238-7587
Email: info@mid-link.net

4. Proposed Device Identification

Proposed Device Name: WEGO-PGLA Absorbable Surgical Suture
Common Device Name: PGLA Synthetic Absorbable Suture

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-PGLA Absorbable Surgical Suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular or neural tissue.

5. Predicate Device Identification

510(k) Number: K122734
Product Name: Aesculap® Novosyn Absorbable Suture
Manufacturer: Aesculap® Inc.

6. Device Description

The WEGO-PGLA Absorbable Surgical Suture is a multifilament (braided), synthetic absorbable suture indicated for use in soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular or neural tissue

It is composed of PGLA suture and needle.

The PGLA Suture is composed of a copolymer made from 90% glycolide and 10% L-lactide (PGLA); it is coated with the copolymer of glycolide and lactide (Polyglactin 370) and calcium stearate. The PGLA suture 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, 3-0, 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 use device.

7. Non-Clinical Test Conclusion

Bench 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
ASTM F88-09, Standard Test Method for Seal Strength of Flexible Barrier Materials;
ASTM F 1140-07 Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Package for Medical Applications;
ASTM F1929-98(2004) Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration
ISO 11135-1:2007 Sterilization of health care products- Ethylene oxide- Part 1: Requirements for development, validation and routing control of a sterilization process for medical devices;
USP <85> Bacterial Endotoxin Limit;
ISO 10993, Biological Evaluation of Medical Devices;
Including:
ISO 10993-3:2003 Biological Evaluation of Medical Devices, Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity;
ISO 10993-5:1999, Biological Evaluation of Medical Devices – Part 5: Test for in vitro cytotoxicity;
ISO 10993-6:1994 Biological Evaluation of Medical Devices, Part6: Test for Local Effects after Implantation;
ISO 10993-10:2002, Biological Evaluation of Medical Devices – Part 10: Tests for irritation and delayed-type hypersensitivity;
ISO 10993-11:1993, Biological Evaluation of Medical Devices – Part 11: Tests for systemic toxicity International Organization for Standardization.

Additionally, the residual strength and absorption rate studies were performed 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 Conclusion

Tab. 1 SE Comparison

ITEM	Proposed Device WEGO-PGLA Absorbable Surgical Suture	Predicate Device K122734 Aesculap® Novosyn Absorbable Suture
Product Code	GAM	Same
Regulation No.	21 CFR 878.4493	Same
Class	II	Same
Sterile	Yes	Yes
Single Use	Yes	Yes
Configuration	PGLA Suture and Needle	Same
Suture		
Material	90% glycolide and 10% L-lactide (PGLA)	Same
Color	Dyed suture (Violet) and Undyed suture	Same
Absorbable/Nonabsorbable	Absorbable	Same
Braided/Monofilament	Braided	Same
Suture Size	The proposed device is available in 6-0, 5-0, 4-0, 3-0, 2-0, 0 and 1, which are the sizes identified in the currently recognized United States Pharmacopoeia.	Available suture sizes are standard according to USP requirements.
Length of Suture	30cm, 45cm, 60cm, 75cm, 90cm, 100cm, 120cm, 150cm, 180cm, 200cm, 250cm, 280cm, 300cm, 320cm, 360cm and 390cm	Unknown
Diameter of Suture	The suture diameters of proposed device comply with the diameter requirement listed in USP 35 <861> Diameter.	Meet the requirements defined in the USP
Tensile strength	The tensile strengths of proposed device comply with the tensile requirement listed in USP 35 <881> Tensile Strength	Meet the requirements defined in the USP
Needle Attachment	The bond between suture and needle of the applicant device meet the requirements defined in USP 35 <871>.	Meet the requirements defined in the USP
Needle		
Material	Stainless Steel	Same
Needle type	Taper, Spatula, Cutting, Blunt	Similar

The proposed device, WEGO-PGLA Absorbable Surgical Suture, is determined to be Substantially Equivalent (SE) to the predicate device, Aesculap® Novosyn Absorbable Suture (K122734), in respect of safety and effectiveness.

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

Foosin Medical Supplies Incorporated, Ltd
% Ms. Diana Hong
PO Box 120-119
Shanghai, 200120
CHINA

January 14, 2014

Re: K130735
Trade/Device Name: WEGO-PGLA Absorbable Surgical Suture
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly(glycolide/l-lactide) surgical suture
Regulatory Class: Class II
Product Code: GAM
Dated: December 2, 2013
Received: December 4, 2013

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
For Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit #10 Indications for Use

510(k) Number: K130735
Device Name: WEGO-PGLA Absorbable Surgical Suture

Indications for Use:

The WEGO-PGLA Absorbable Surgical Suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular or neural tissue.

☒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 ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K130735