December 14, 2017

Nantong Holycon Medical Devices Co., Ltd.
% Ms. Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119
Shanghai, 200120 China

Re: K173043
Trade/Device Name: Holycon Synthetic Absorbable Sutures
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(Glycolide/L-Lactide) Surgical Suture
Regulatory Class: Class II
Product Code: GAM
Dated: September 26, 2017
Received: September 28, 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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)*

K173043

Device Name

Holycon Synthetic Absorbable Sutures

Indications for Use *(Describe)*

The Holycon Synthetic Absorbable Sutures 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.

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.

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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: K173043

1. Date of Preparation: 12/12/2017

2. Sponsor Identification

Nantong Holycon Medical Devices Co., Ltd.
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jing Cheng (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: Holycon Synthetic Absorbable Sutures
Common Name: PGLA Synthetic Absorbable Suture
Size: USP 6-0, USP 5-0, USP 4-0, USP 3-0, USP 2-0, USP 0 and USP 1

Regulatory Information
Regulation Description: Absorbable poly (glycolide/l-lactide) surgical suture
Classification: II
Product Code: GAM
Regulation Number: 21 CFR 878.4493
Review Panel: General & Plastic Surgery

Indications for Use:

The Holycon Synthetic Absorbable Sutures 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.

Device Description

The Holycon Synthetic Absorbable Sutures are 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.

The Holycon Synthetic Absorbable Sutures are composed of PGLA suture and needle.

The Holycon Synthetic Absorbable Sutures are composed of a copolymer made from 90% glycolide and 10% L-lactide (PGLA); they are coated with copolymer of 30% glycolide and 70% lactide and calcium stearate. The PGLA suture is dyed suture.

The needles are available in four types: Taper, Cutting, Spatula and Blunt. The material of needles is stainless steel.

The performance of this absorbable suture complies with United States Pharmacopeia (U.S.P.) monograph requirements for Absorbable Surgical Suture, USP 40<861>, USP 40<871> and USP 40 <881>.

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

5. Identification of Predicate Device

510(k) Number: K130735
Product Name: WEGO-PGLA Absorbable Surgical Suture
Manufacturer: Foosin Medical Supplies Inc., Ltd

6. Non-Clinical Testing

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 40-NF 35:2017 <861> Sutures – Diameter;
- USP 40-NF 35:2017 <871> Sutures - Needle Attachment;
- USP 40-NF 35:2017 <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 40-NF 35:2017 <85> Bacterial Endotoxins Test;
- ASTM F88/F88M-09 Standard Test Method for Seal Strength of Flexible Barrier Materials;
- 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;
- USP <151> Pyrogen Test

The in vivo tensile strength testing, which is to determine the in vivo breaking strength retention study, was conducted in subcutaneous implantation study, and the testing was conducted with the predicate device as a control.

The 3-year real-time aging tests were conducted to support that the proposed device to mitigate the risk

of time-dependent degradation of the suture material. The real-aging testing includes package integrity, stability and physical test.

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 Holycon Synthetic Absorbable Sutures**	**Predicate Device WEGO-PGLA Absorbable Surgical Suture, K130735**
Product Code	GAM	GAM
Regulation Number	21 CFR 878.4493	21 CFR 878.4493
Class	II	II
Intended Use	The Holycon Synthetic Absorbable Sutures 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.	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.
Material	90% glycolide and 10% L-lactide (PGLA)	90% glycolide and 10% L-lactide (PGLA)
Color	Dyed	Dyed and Undyed
Absorbable / Non-absorbable	Absorbable	Absorbable
Braided / Monofilament	Braided	Braided
Sterility	EO Sterilized	EO Sterilized
Suture Size	USP 6-0, USP 5-0, USP 4-0, USP 3-0, USP 2-0, USP 0 and USP 1	USP 6-0, USP 5-0, USP 4-0, USP 3-0, USP 2-0, USP 0 and USP 1
Length of Suture	45cm, 75cm, 90cm and 150cm	30cm, 45cm, 60cm, 75cm, 90cm,100cm, 120cm, 150cm, 180cm, 200cm, 250cm, 280cm, 300cm, 320cm, 360cm and 390cm
Single Use	Yes	Yes
Performance	Comply with: USP <861> USP <871> USP <881>	Comply with: USP <861> USP <871> USP <881>
Biocompatibility	Conforms to the requirements of ISO 10993 series Standards	Conforms to the requirements of ISO 10993 series Standards

The main differences between proposed device and predicate device are color and length of suture. There is only dyed suture available for proposed device, and the suture length range of proposed

device is smaller than that of the predicate device, the dyed suture and suture length range of proposed device are included in predicate device.

9. Substantially Equivalent (SE) Conclusion

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