August 26, 2022

Gunze Limited
% Stuart Goldman
Senior Consultant
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, Texas 78746

Re: K221487
Trade/Device Name: NEOVEIL Staple Line Reinforcement
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OXC
Dated: July 27, 2022
Received: July 27, 2022

Dear Stuart Goldman:

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 Deborah Fellhauer
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221487

Device Name
NEOVEIL® Staple Line Reinforcement

Indications for Use *(Describe)*
NEOVEIL® Staple Line Reinforcement is indicated for use in surgical procedures in which soft tissue transection or resection with staple line reinforcement is needed. NEOVEIL® Staple Line Reinforcement can be used for reinforcement of staple lines during lung resection, liver resection, bronchial, bariatric, colon, colorectal, esophagus, gastric, mesentery, pancreas, and small bowel 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Special 510(k) Summary
NEOVEIL® Staple Line Reinforcement

1. Submission Sponsor

GUNZE LIMITED
Medical Division
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Ayabe, Kyoto
Japan 623-8513
Contact: Mr. Hidenori Nishioka
Title: Regulatory Affairs

2. Submission Correspondent

Emergo Global Consulting, LLC
2500 Bee Cave Road
Building 1, Suite 300
Austin, TX 78746
Contact: Mr. Stuart R. Goldman
Title: Sr. Consultant RA/QA

3. Date Prepared

August 23, 2022

4. Device Identification

Type of 510(k):	Special 510(k)
Trade Name:	NEOVEIL® Staple Line Reinforcement
Product Code:	OXC
Classification Name:	Mesh, Surgical, Absorbable, Staple Line Reinforcement
Regulation Number:	21 CFR 878.3300
Regulation Description:	Surgical Mesh
Device Class:	2
Review Panel:	General & Plastic Surgery

5. Legally Marketed Predicate Device

Trade Name:	NEOVEIL™ Tube/Sheet Type Suture and Staple Line Reinforcement Material
510(k) No.:	K130997
Manufacturer:	GUNZE LIMITED

The predicate device has not been subject to a design related recall.

6. Indications for Use

NEOVEIL® Staple Line Reinforcement is indicated for use in surgical procedures in which soft tissue transection or resection with staple line reinforcement is needed. NEOVEIL® Staple Line Reinforcement can be used for

reinforcement of staple lines during lung resection, liver resection, bronchial, bariatric, colon, colorectal, esophagus, gastric, mesentery, pancreas, and small bowel procedures.

7. Device Description

NEOVEIL® Staple Line Reinforcement is composed of a biodegradable synthetic polymer, polyglycolic acid (PGA) and is offered as a nonwoven surgical mesh configured into sleeves. The device is applied to the surgical site via a mechanical stapler with two jaws, where one piece of the sleeve is slid over each jaw of the stapler. This is accomplished by attaching a similar-sized piece of nonabsorbable elastic knit to the PGA felt that is held together by means of PGA tacking threads. After deployment of the tube type reinforcement material, the non-degradable elastic knits, comprised of polyurethane and nylon, are removed and discarded along with the PGA tacking sutures. The PGA material is dyed with D&C Green No.6.

8. Device Changes

This Special 510(k) is being made by GUNZE to modify one of their existing NEOVEIL™ Tube/Sheet Type Suture and Staple Line Reinforcement Material model devices cleared under K130997. The modification gives that device longer tacking threads to better facilitate its use during certain endoscopic procedures when used with certain stapler guns. A new catalogue number has also been given to this new model. In addition, the trade name of the subject device is also being changed to NEOVEIL® Staple Line Reinforcement to better reflect its intended use.

9. Substantial Equivalence Discussion

Except for the minor differences in the size of the absorbable PGA felt and elastic knit and the length of the PGA tacking threads found in NEOVEIL® Staple Line Reinforcement as described above when compared to those same components found in NEOVEIL™ Tube/Sheet Type Suture and Staple Line Reinforcement Material (K130997), the subject device is equivalent to the predicate device in intended use, indications for use, technological characteristics and performance.

10. Non-Clinical Performance Testing

As part of demonstrating substantial equivalence of the subject device to the predicate device, GUNZE conducted side-by-side non-clinical performance testing in the form of a simulated usability testing on final finished versions of NEOVEIL®™ using a relevant mechanical stapler that received FDA 510(k) clearance. The non-clinical performance testing was done to internal GUNZE test methods. The test methods used were selected based on the 510(k) Premarket Notification of the predicate device (K130997). The performance testing validated that NEOVEIL® Staple Line Reinforcement meets its product specification and performs as intended. Results confirm that the specification requirements for the subject device have been met.

- Non-Clinical Performance Testing:
  - GUNZE internal test method for stapler insertion and removal forces with NEOVEIL®™
  - GUNZE internal test method for stapler firing force with NEOVEIL®™
  - GUNZE internal test method for staple formation with NEOVEIL®™
- Usability:
  - IEC 62366-1:2015, *Application of Usability Engineering to Medical Devices*
- Risk Analysis:

- ISO 14971:2019, *Application of Risk Management to Medical Devices*

11. Clinical Performance Data

Not applicable to this submission.

12. Substantial Equivalence Conclusion

NEOVEIL® Staple Line Reinforcement has the same intended use and indications for use as the previously cleared predicate device, NEOVEIL™ Tube/Sheet Type Suture and Staple Line Reinforcement Material. The addition of the new size of the subject device and increase in length of the tacking threads for use with other brands of mechanical staplers has been addressed with non-clinical performance testing to well established GUNZE test methods. The test results and analysis support a determination of substantial equivalence of NEOVEIL® Staple Line Reinforcement to the predicate device in terms of safety, effectiveness and performance.