December 9, 2022

Lydus Medical Ltd.
℅ Orly Maor
Regulatory consultant
25 Sirkin Street
Kfar Saba, 4442156
Israel

Re: K221280
Trade/Device Name: Vesseal
Regulation Number: 21 CFR 878.5020
Regulation Name: Nonabsorbable Polyamide Surgical Suture
Regulatory Class: Class II
Product Code: GAR
Dated: October 26, 2022
Received: November 4, 2022

Dear Orly Maor:

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,

Ankurita Datta -S

Digitally signed by Ankurita Datta -S
Date: 2022.12.09 12:47:47 -05'00'

for Katherine Trivedi
Acting Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

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)*
K221280

Device Name
Vesseal

Indications for Use *(Describe)*

The Vesseal is intended for use in the delivery of 8 interrupted sutures to assist the surgeon in the creation of a vascular anastomosis in arteries of 2-4mm in diameter.
It is not intended for use in coronary artery grafts.

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
K221280

Date Prepared: December 8, 2022

I. SUBMITTER

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II. DEVICE

Device Trade Name: Vesseal
Device Common Name: Suture, Nonabsorbable, Synthetic, Polyamide
Classification: 21 CFR 878.5020
Class: Class II
Product Code: GAR

III. PREDICATE DEVICE

- K192420, Kono Seisakusho Co., Ltd. Crownjun Nylon Suture
- K013683, Abbott Vascular Suture Anastomosis device

IV. DEVICE DESCRIPTION

The Vesseal is a hand-held device, enabling simultaneous deployment of 8 double-armed 9-0 to 7-0 nylon sutures (USP certified). The sutures are delivered from the inside out, around the circumference of two ends of blood vessels (ranging in size from 2mm to 4mm) to assist in the creation of a microvascular anastomosis.

The Vesseal is comprised of two main mechanisms:

1. The needle insertion mechanism contains two rod protrusions, intended for locating the blood vessel, opening, mounting, and positioning them relative to the stopper mechanism. Each rod

stores, 8 curved needles that allow the transition of the double-armed nylon sutures during deployment.

2. The handle deployment mechanism features right and left switches to deploy the needles on the respective rod side, and the gear to rotate the rod and enable access to its entire perimeter.

V. INDICATIONS FOR USE

The Vesseal is intended for use in the delivery of 8 interrupted sutures to assist the surgeon in the creation of a vascular anastomosis in arteries of 2-4mm in diameter.
It is not intended for use in coronary artery grafts.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Vesseal has the same intended use as the predicate device(s) and the indications for use are similar to that of the predicate device(s). A comparison of the Vesseal and predicate devices is provided in the table below:

	Lydus Ltd. Vesseal	**Kono Seisakusho Co., Ltd. Crownjun Nylon Suture**	**Abbott Vascular Suture Anastomosis Device**	**SE Justification**
510(k) number	K221280	K192420	K013683	
Product Code	GAR	GAR	GAW	Same as the predicate
CFR	878.5020	878.5020	878.5010	Same as the predicate device Crownjun Nylon Suture
Intended Use	The Vesseal is intended for use in the delivery of 8 interrupted sutures to assist the surgeon in the creation of a vascular anastomosis in arteries of 2-4mm in diameter. It is not intended for use in coronary artery grafts.	CROWNJUN Nylon Suture is intended to join the edges of soft- tissue wound or incision to ligate soft tissues.	The Abbott Vascular Suture Anastomosis device is intended for use in the delivery of 10 interrupted sutures to assist the surgeon in the creation of a vascular anastomosis.	Same as the predicate. The exclusion of using the device for coronary artery graft does not change the intended use.
Suture Materials	Nylon	Nylon	Polypropylene	Same as the predicate.
Suture Size	USP 7-0 to USP 9-0	Ranging from USP size 12-0 through USP 0	USP 7-0	Same within the range. The additional sizes do not alter device safety or effectiveness as demonstrated in the testing.

Number of Sutures	8	N/A	10	Similar- within the predicate device number of sutures
Anastomosis type	End-to End	N/A	End-to End and Side-to-Side	Same- within the predicate device features
Delivery Method	Needle passed through the tissue with suture attached	N/A	Needle passed through the tissue with suture attached	Similar to the predicate device
Delivery Needle	Material-Stainless Steel Taper point	N/A	Material-Unknown Taper point	Similar to the predicate device
Sterilization	EtO	EtO	EtO	Same
How Provided	Single use, sterile	Single use, sterile	Single use, sterile	Same

VII. PERFORMANCE DATA

The following performance data were used to support of the substantial equivalence determination:

- Biocompatibility testing on the Vesseal delivery device and suture material (including long-term and short-term biocompatibility endpoints)
- Sterilization, Packaging, and Shelf-Life testing per ISO 11135-1
- Bench Testing including dimensional verification, corrosion, simulated use, needle penetration, suture and needle attachment, suture knot pull testing, bending and bonding process qualification
- Usability testing to evaluate the use-related safety and effectiveness of Vesseal when used by qualified user via observational data, knowledge task data, and interview data.
- A comparative GLP Animal Study

VIII. CONCLUSION

The Vesseal is substantially equivalent to the predicate devices in indications for use, fundamental scientific technology, and technological characteristics.