June 17, 2021

Anchora Medical, Ltd.
℅ Esther Kott
RA Consultant
Duet-Medical Consulting Ltd.
10 HaAnafa Street POB536
Zur Moshe, 42810
Israel

Re: K201744
Trade/Device Name: Su2ura Approximation Device
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OCW
Dated: June 25, 2020
Received: June 25, 2020

Dear Esther Kott:

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 and Part 809); 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,

Cindy Chowdhury, Ph.D., M.B.A.
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)*
K201744

Device Name
Su2ura® Approximation Device

Indications for Use *(Describe)*
The Su2ura® Approximation Device is indicated in endoscopic surgery for the placement of interrupted or running stitches in soft 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

K201744

Owner's Name & Address	Anchora Medical, Ltd. Leshem St., 1 Industrial Park Caesarea, 3088900 Israel Phone: +972-54-777-6615
Contact Person	Esther Kott Regulatory Consultant Phone: +972-58-488-7454 Email: esther@ldp-consulting.com
Date	June 15, 2021
Trade Name	Su2ura® Approximation Device
Common / Classification Name	Endoscopic tissue approximation device
Product Code	OCW
Classification	21 CFR 876.1500
Predicate Device	K082659, Modified Endo Stitch
Device Description	The Anchora Su2ura® Approximation Device is a sterile single use device is indicated in endoscopic surgery for the placement of interrupted or running stitches in soft tissue. The device is a 5mm single-use endoscopic suturing device loaded with threaded anchors. It is designed to deploy up to 19 anchors by a trigger action of the handle of the delivery system. After deployment, each anchor is anchored within the tissue in which it was deployed. After deployment of 2 or more anchors, the suture that passes between the anchors can be tightened to pull the anchors toward each other and approximate the tissue. The delivery system consists of a plastic handle and a 36-cm stainless steel shaft. The handle includes a Trigger, a Knob, and a Toggle Button. A Cap can be added at the distal edge of the Shaft to advance extracorporeal suture knots. The anchors can be deployed in single-stitch or running-stitch configuration. The device deploys the anchors through a needle with an outer diameter of 2.1 mm, available in two

lengths: 5 mm and 9 mm protrusion. The Anchor is advanced outside of the needle by a Pushrod. Each anchor, made of stainless steel, is threaded with an off-the-shelf UHMWPE suture manufactured by Teleflex Medical. The device provides the anchors already threaded on this suture.

The device is sterile packaged and designed for single use only. The device is manufactured from medical grade materials (mainly plastics and stainless steels).

Indications for Use

The Su2ura® single-use suturing device is indicated in endoscopic surgery for the placement of interrupted or running stitches in soft tissue.

Technological Characteristics and Substantial Equivalence Comparison with the Predicate

Characteristic	**Modified Endo Stitch [predicate device]**	**Su2ura Approximation Device [subject device]**
510(k) number	K082659	K201744
Product Code	OCW	OCW
Intended Use/Indications for Use	The Modified Endo Stitch™ 10 mm single- use suturing device has application in endoscopic surgery for the placement of interrupted or running stitches in soft tissue.	The Su2ura® single-use suturing device is indicated in endoscopic surgery for the placement of interrupted or running stitches in soft tissue.
Number of uses	Single use only	Same
Use Environment	Operating room	Same
Intended user	Physicians having adequate training and familiarity with endoscopic techniques	Same
Working length	Working length: 38 cm	Similar (36 cm)
Shaft diameter	Outer diameter: 10 mm	Outer diameter: 5.4 mm
Port size	10mm	5mm
Delivery System construction and materials	Plastic handle, stainless steel shaft and needle	Similar
Implant materials	4 sutures materials are compatible with the Endo Stitch: • Surgidac™ (0 and 2-0) • Polysorb™ (0,2-0,3-0 and 4-0) • Bralon™ (0 and 2-0) Sofsilk™ (0 and 2-0)	Suture: Force Fiber® Polyethylene Non-Absorbable Surgical Sutures by Teleflex Medical, non-absorbable surgical thread, USP 0, cleared under K172016, K150438, K100506, K070673, K063778, K040472 and K033654 Anchors:

		Stainless Steel 316 LVM, per ASTM F138 Each device consists of 19 implants
Graduation on shaft	Yes – cm	Same
Handling	One-handed instrument, dominant or non-dominant	Same
Suture placement	The device holds and passes a needled suture between its two jaws. The suture needle is passed from one jaw to another by squeezing the opposing handles and securing it in each jaw by activating the toggle lever. The device needs to approach the two sides of the tissue being sutured.	The device pushes and passes an anchored suture through the needle by squeezing the handle's trigger lever. The device features a retracting shaft exposing a needle at its distal end. The device needs to approach one side of the tissue deploying a T anchor.
Suture location	The suture is placed through and into the tissue.	Same
Suturing type	Interrupted stiches and running stitches	Same
Knot tying type	Intracorporeal and extracorporeal square knots, surgeons' knot and a variety of slip knots	Same
Needle	Curved stainless steel, exposed	Straight stainless steel, hidden
Stitch profile	O-shaped stitch	U-shaped stitch
Stitch/Anchor Depth	Up to 19mm	Up to 13 mm
Sterilization	Supplied sterile by EtO (SAL of 10^{-6})	Same
Biocompatibility	All patient contact materials have been evaluated in accordance with ISO 10993-1	Same
Performance Data	In-vitro and in-vivo testing has been performed in support of the intended use of this device	Same

Non-Clinical Performance Data

Appropriate product testing was performed to evaluate conformance to USP requirements, applicable standards, product specifications, and equivalence to the predicate design. The device was evaluated against individual functional and reliability requirements.

<u>Performance Testing</u>

	Bench testing included dimensional verification, component compatibility, tissue anchoring pull-out, corrosion testing per ASTM F2129, deployment reliability, suture pull-out strength, and tensile strength per USP <881>. MRI Safety and Compatibility MRI safety and compatibility was verified per ASTM F2052, ASTM F2213, ASTM F2182, and ASTM F2119. The device was deemed MR Conditional. Packaging Integrity Packaging Integrity was confirmed by testing in accordance with ASTM F1929-15, ASTM DI69-16 and ASTM F1886/F1886M-16. The results of all studies confirmed substantial equivalence between the subject and predicate designs.
Biocompatibility	Biocompatibility assessments were performed in accordance with the appropriate risk category requirements, as defined in ISO 10933-1. Testing included extractable and leachable studies in accordance with ISO 10993-18 and a toxicological risk assessment in accordance with ISO 10993-17.
HFE Study	A Human Factors Engineering Study was performed to verify the usability of the device. The study was performed with 18 representative users, and evaluated the usability of all tasks needed to use the device. The study confirmed device usability and demonstrated that the training provided to users and the Instructions for Use of the device were clear and accurate. These data support the safety and effectiveness of the Su2ura Approximation Device for its intended use.
Pre-Clinical Performance Data	An animal study was performed to assess the safety and performance of the device, under GLP conditions and in compliance with ISO 10993-6. The study included 8 pigs, each subjected to a series a surgical incisions. Separate animals were employed for the Test (N=5) and Control Items (N=3). All incisions were closed with the Test or Control Items, and the animals were monitored clinically for 13 weeks before sacrifice. All incision sites were successfully closed by either Test or Control Items, and histopathological data indicated that long-term safety was similar between the Test and Control Items.
Clinical Performance Data	Clinical testing was not required to demonstrate substantial equivalence.

Substantial Equivalence	The Anchora Su2ura® has very similar indications for use and technological features to the predicate device. The minor differences in technological characteristics do not raise new types of safety or effectiveness questions. Bench, animal and human factors testing confirms that these differences do not adversely impact performance. Therefore, the proposed device is substantially equivalent to the predicate device.
Conclusion	Based on the intended use, technological characteristics, performance testing and comparison to the predicate device, the subject device is substantially equivalent to the predicate device and raises no different questions of safety or effectiveness.