March 26, 2020

Medeon Biodesign, Inc.
Tsung-Yu Hsieh
Sr. Specialist of Regulatory, Quality and Clinical Affairs
7F, 116, HouGang St.,
Taipei, 11170 Tw

Re: K193652
Trade/Device Name: AbClose - Port Site Closure Device
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OCW, GCJ, HCF
Dated: December 26, 2019
Received: December 30, 2019

Dear Ms. Hsieh:

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,

Cindy Chowdhury, Ph.D., M.B.A.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193652

Device Name
AbClose - Port Site Closure Device

Indications for Use *(Describe)*
The AbClose - Port Site Closure Device has application in laparoscopic procedures for approximation of tissues and percutaneous suturing for closing incision sites.

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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510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted as part of the Premarket Notification in compliance with requirements of CFR Part 807, Subpart E and Section 807.92.

The assigned 510(k) Number: K193652
Date Prepared: March 4, 2020

1 **Submitter**

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2 **Device Name**

Common or Usual Name	Endoscopic tissue approximation device
Trade Name	AbClose™ - Port Site Closure Device
Product Code	OCW, GCJ, HCF
Device	Endoscope and accessories
CFR Classification	CFR Part 876.1500
Device Class	II
Classification Panel	Gastroenterology/Urology

3 **Predicate k number** K160117

4 **Device Description:** The AbClose™ - Port Site Closure Device is a sterile, single-use device including 2 major components, Suture Guide and Suture Passer. The device is used with a commercially cleared suture, and is used as a manual instrument to pass needles with suture through soft tissues for suturing. The device is designed with a suture retrieval system for unassisted fascial closures, facilitating standard suture closure techniques.
The Suture Guide is structured by a Handle and a Suture Catcher. The pyramid-shape Suture Catcher is controlled by a Push Button to fold

the Suture Catcher into cylinder shape for insertion into the trocar wound. Once the Suture Guide is in position, Suture Catcher is expanded back to a pyramid shape to stabilize the device on the trocar wound site.
The Suture Passer is a handheld suture grasping device designed to pass sutures through soft tissue. It features a Handle and a stainless steel Needle assembled with a Suture Shaft that grasps a suture. The Suture Passer is designed to work with the Suture Guide to penetrate through soft tissues and deploy suture ends into the Suture Catcher. Withdraw Suture Guide by folding the Suture Catcher into cylinder shape, the two suture ends are securely captured and are ready for user to type knots to close the trocar wound site.
The AbClose™ - Port Site Closure Device is intended to be used by clinicians through prescription use only.

5 **Indications for Use:** The AbClose™ - Port Site Closure Device has application in laparoscopic procedures for approximation of tissues and percutaneous suturing for closing incision sites.

Special Conditions for Use Statement(s): For prescription use only

6 **Technological Characteristics and Substantial Equivalence Comparison with Predicate**: Modifications to design and material of the previously 510(k) cleared AbClose™ - Port Site Closure Device (K160117) to close the incision created by 10 - 15mm trocar. The modifications include:

1. Dimensional change: Change component dimension to improve the functionality of device, simplify the production process and improve manufacturability.
2. Material change: Change material of Slider to improve manufacturability and use material of Button Lock with higher tensile and flexural strength.
3. Add visualization feature: Add visualization windows on Slider and add indication marks on Handle of Suture Passer and Suture Guide.
4. Package change: Dimensional and structure change of packaging components includes reducing the size of sterile barrier system, modifying the securing features of Blister, add Lid of Blister and reduce the size and change the structure of protective packaging material.

A comparison of the device features, intended use, and other information demonstrates that the modified device is substantially equivalent to the predicate device as summarized in **Table 1**.
The differences raise no different questions of safety or effectiveness.

Table 1: Substantially Equivalent Table

Similarities		
Device name	**Predicate device: AbClose™ - Port Site Closure Device (Model: M12) (K160117)**	**Modified device: AbClose™ - Port Site Closure Device (Model: M12)**
Indications for use	The AbClose™ - Port Site Closure Device has application in laparoscopic procedures for approximation of tissues and percutaneous suturing for closing incision sites.	Same
Target patient Population	Patient under laparoscopic surgery	Same
Target User Population	Clinician who is qualified to participate a laparoscopic surgery.	Same
Anatomical Site	Abdominopelvic cavity	Same
Where Used	Hospital O.R. room	Same
Contraindications	Do not use where laparoscopic techniques are generally contraindicated	Same
Method of Introduction	-Suture Guide is introduced into abdominopelvic cavity via a 10 – 15 mm trocar port site -Suture Passer is introduced into abdominopelvic cavity by insertion	Same
Performance	Maintain pneumoperitoneum and facilitate placement and withdrawal of suture loop	Same
Biocompatible for Intended Use	Limited exposure, external communication device of tissue contact.	Same
Sterilization Method	Ethylene Oxide sterilization, SAL of 10^{-6}	Same
Energy source	No energy source	Same
Compatibility	**Trocar:** 10 – 15 mm	Same

7. Performance Testing

The following performance testing for the design modification demonstrated substantial equivalence to the previously cleared predicate:

Biocompatibility testing

Per material change, the biocompatibility evaluation and testing of the AbClose™ - Port Site Closure Device was conducted in accordance with the following standards and guidance, as recognized by the FDA:

- FDA Guidance - Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"
- ISO 10993-5:2009, Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2009, 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.
- United State Pharmacopeia (USP) Chapter <151> Rabbit Pyrogen Test

Mechanical testing

The modified device's mechanical function and structure integrity were tested and demonstrated that the design specification from design input were fulfilled and the design modifications did not alter the device safety and function. The following mechanical tests have been successfully performed with the same test methods as for the predicate device, and all the results were passed, including Suture Guide Push Button Test, Suture Guide Slider Test, Suture Guide Durability Test, Suture Guide Front Upper Cover Bonding Test, Suture Guide Front Lower Cover Bonding Test, Suture Passer Suture Button Test, Suture Passer Suture Release Button Test, Suture Passer Penetration Test, Suture Passer Cover Bonding Test, Suture Deployment Test, Suture Guide Lock Mechanism Test, and Accelerated Aging test of sterile barrier system. In addition to the original tests conducted for the predicate device, three new tests have been conducted to verify the effectiveness of the modifications made in the modified device, including Suture Guide Suture Catcher Torque Test, Suture Passer Needle Retention Force Test, and Suture Passer Needle Torque Test. These mechanical tests have been successfully performed, and all the results were passed.

Functional testing

Device functionality was tested in the animal model to demonstrate that the intended use was fulfilled. Design modifications did not alter the device function and intended use. The animal study has been successfully performed with the same test method as that used for the predicate device, and the result was passed.

8. Conclusion

Based on the intended use, technological characteristics, performance testing and comparison to the predicate device, the modified device is substantially equivalent to the predicate device and raises no different questions of safety or effectiveness.