DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 30, 2016

Medeon Biodesign, Inc.
Ms. Greta Chang
Sr. Manager of Regulatory, Quality & Clinical Affairs
7F, 116, HouGang St.
Taipei
Taiwan 11170 TW

Re: K160117
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: July 27, 2016
Received: July 28, 2016

Dear Ms. Greta Chang:

This letter corrects our substantially equivalent letter of September 9, 2016.

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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)*
K160117

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

510(k) Number K160117
Date Prepared 16 June 2016

1. **Submitter**

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Date Prepared	

2 **Device Name**

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

3 **Predicate Device Name**

510(k) number:	K132362
Trade or proprietary or model name:	WECK EFx Endo Fascial Closure System
Manufacturer:	Teleflex Medical, Incorporated

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 fold 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**:	A Comparison of the device feature, intended use, and other information demonstrates that the AbClose - Port Site Closure Device is substantially equivalent to the predicate device as summarized in Table 1.
7.	**Materials**	All patient contacting materials are in compliance with ISO 10993-1, as well as FDA Draft Guidance – Use of international Standard ISO 10993, “Biological Evaluation of Medical Devices, Part1: Evaluation and Testing”, dated 04-23-2013

Table 1

Similarities		
Device name	**Subject device: AbClose - Port Site Closure Device**	**Predicate device: WECK EFx Endo Fascial Closure System**
Indications for use	The AbClose - Port Site Closure Device has application in laparoscopic procedures for approximation of tissue and percutaneous suturing for closing incision sites.	The WECK EFx Endo Fascial Closure System has application in laparoscopic procedures for approximation of tissue and percutaneous suturing for closing incision sites.
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 10-15mm trocar port site -Suture Passer is introduced into abdominopelvic cavity by insertion	Same
Compatibility Other Devices	Trocar: 10~ 15 mm	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
Differences		
Sterilization Method	Ethylene Oxide sterilization, 10^{-6} SAL	Radiation, 10^{-6} SAL

7. Performance Testing

Performance testing has been carried out to demonstrate that this device meets the performance specification for its intended use. The following tests were performed on the device.

Sterilization validation

Sterilization validation was conducted in accordance with ISO 11135:2014 “Sterilization of health-care products—Ethylene oxide –Requirement for the development, validation and

routine control of a sterilization process for medical devices". Sterilization has been validated to achieve a Sterility Assurance Level (SAL) of 10^{-6}.

Mechanical testing

Abclose - Port Site Closure Device's mechanical function and structure integrity were tested to demonstrate that the design specification from design input are fulfilled.
Mechanical safety test were also conducted to demonstrate the insertion portion of the device remain intact during the surgery and raise no safety concern.

Animal test

The intended use has been conducted by animal test to demonstrate the AbClose - Port Site Closure Device can deliver the intended function of application in laparoscopic procedures for approximation of tissues and percutaneous suturing for closing incision sites.

8. Conclusion

Base on the intended use and/ or indications for use, technological characteristics, performance testing and comparison to predicate device, the AbClose - Port Site Closure Device is substantially equivalent to the predicate device.