

K132362

510(k) SUMMARY
WECK® EFX™ Endo Fascial Closure System

A. Name, Address, Phone and Fax Number of Applicant

Teleflex Medical, Incorporated
2917 Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 919-361-4071
Fax: 919-433-4996

B. Contact Person

Natalie Hichak
Regulatory Affairs Specialist

Lorraine DeLong
Manager RA/QE Surgical

OCT 08 2013

C. Date Prepared

July 16, 2013

D. Device Name

Trade Name: WECK® EFX™ Endo Fascial Closure System

Common Name: Endoscopic tissue approximation device

Classification Name: Endoscope and accessories

E. Device Description

Laparoscopic ports are used to establish a port of entry into the abdominal cavity and gain access to the surgical site. Ports are positioned into patients during minimally invasive surgical procedures by trained surgeons in order to provide a pathway for the insertion and removal of surgical devices and removal of specimens. Following the laparoscopic procedure the injury to the abdominal wall defects at the site of the port entry puncture must be repaired and often entails suturing to prevent future complications and particularly herniation. The WECK® EFX™ Endo Fascial Closure System is designed to maintain pneumoperitoneum and facilitate placement and withdrawal of suture loops to perform these repairs.

F. Indications for Use

The WECK® EFX™ Endo Fascial Closure System has application in laparoscopic procedures for approximation of tissues and percutaneous suturing for closing incision sites.

G. Contraindications

Do not use where laparoscopic techniques are generally contraindicated

H. Substantial Equivalence

The proposed WECK® EFX™ Endo Fascial Closure System is substantially equivalent to the predicate devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Axiom Fascial Closure System	Axiom Technology Partners	K103412	December 30, 2010

I. Comparison To Predicate Devices

The proposed WECK® EFX™ Endo Fascial Closure System has the same technology, indications for use and functional characteristics as the predicate system. This submission is notification to the agency of the transfer in ownership of the 510(k) K103412 from Axiom Technology Partners LLC to Teleflex Medical Incorporated and to update material and dimensional modifications incorporated subsequent to the clearance of 510(k) K103412 and prior to the transfer of ownership to Teleflex Medical Inc.

J. Materials

All patient contacting materials are in compliance with ISO10993-1.

K. Technological Characteristics

A comparison of the technological characteristics of the proposed WECK® EFX™ Endo Fascial Closure System and the predicate has been performed. The results of this comparison demonstrate that the WECK® EFX™ Endo Fascial Closure System is equivalent to the marketed predicate devices in performance characteristics.

L. Performance Data

The bench testing has been performed to verify that the performance of the proposed WECK® EFX™ Endo Fascial Closure System is substantially equivalent to the

predicate device. The proposed material and dimensional modification was tested according to the scheme and specifications summarized below.

Performance Data Results Summary		
Response Type	Test Specification	Result
Qualitative	Material Verification	PASS Materials were found to meet pre-established specifications.
Qualitative	Visual Inspection for Defects and Cleanliness	PASS All devices passed the inspections for defects and cleanliness.
Quantitative	Dimensional Inspection	PASS Dimensions were found to meet pre-established specifications.
Qualitative and Quantitative	Mechanical Inspection	PASS Function of the device was verified against pre-established specifications.
Qualitative and Quantitative	Suture Retention	PASS Function of the device was verified against pre-established specifications.
Qualitative and Quantitative	Destructive Testing of Failure Modes	PASS The device exceeded the maximum working load of the pre-established specifications.

L. Conclusion

Based upon the comparative test results, the proposed WECK® EFX™ Endo Fascial Closure System is substantially equivalent in performance to the predicate devices cleared to market via 510(k) K103412. The modifications made to the proposed WECK® EFX™ Endo Fascial Closure System do not introduce any new issues of safety and effectiveness.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - W066-G009
Silver Spring, MD 20993-0002

Teleflex Medical, Incorporated
Ms. Natalie Hichak
Regulatory Affairs Specialist
2917 Weck Drive
Research Triangle Park, North Carolina 27709

October 8, 2013

Re: K132362
Trade/Device Name: WECK³⁰ EFX™ Endo Fascial Closure System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Codes: OCW, GCJ, HCF
Dated: July 29, 2013
Received: July 30, 2013

Dear Natalie Hichak,

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

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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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

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Indications for Use:

The WECK® EFX™ Endo Fascial Closure System has application in laparoscopic procedures for approximation of tissues and percutaneous suturing for closing incision sites.

Prescription Use XX
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-counter use __
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S