510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Weck® Metal Ligating Clips

NOV 27 2013

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

Teleflex Medical, Incorporated
2917 Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 919-433-8065
Fax: 919-433-4996

B. Contact Person

Ashlea Ricci, RAC
Senior Regulatory Affairs Specialist

Lorraine DeLong
Manager RA/QE Surgical

C. Date Prepared

August 23, 2013

D. Device Name

Trade Name:	Weck® Metal Ligating Clips
Common Name:	Implantable Clips
Classification Name:	Clips, Implantable

E. Device Description

Weck® Metal Ligating Clips are single-use, non-absorbable, non-active implantable devices designed for use in general surgical procedures that require vessel or tissue ligation. Each product line possesses a unique design necessary for compatibility with its appropriate Weck® ligating clip applier. The clips are available in a range of sizes, allowing the end user to ligate a wide range of vessels and tissue structures. Weck® Metal Ligating Clips are manufactured from medical grade titanium, tantalum or stainless steel alloys and are provided prepackaged in color-coded cartridges, which are provided as single-use, sterile devices.

Accessories to the Weck® Metal Ligating Clips include manual clip appliers and removers for use in both general open and endoscopic procedures. Both the appliers and removers are multiple use, non-sterile devices that require cleaning and sterilization prior to each use.

F. Indications for Use

Weck® Ligating Clips are intended for use in procedures involving vessels or anatomic structures for which the surgeon determines ligating clips are the best choice. Surgeons should select the size, type and material of the clip based upon their experience, judgment and needs.

G. Contraindications

Weck® Ligating Clips are not intended for use as a contraceptive tubal occlusion device.

Weck® Ligating Clips are contraindicated for use in ligating the renal artery during laparoscopic donor nephrectomies.

H. Environmental Conditions

Weck® Metal Ligating Clips are "MR Conditional" up to and including 3-Tesla MR environments.

I. Substantial Equivalence

The proposed Weck® Metal Ligating Clips are substantially equivalent to the predicate devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Horizon™ Ligating Clip	Teleflex Medical (Weck)	K982313	08/10/1998
Hemoclip® Traditional Ligating Clip	Teleflex Medical (Weck)	K841547	08/14/1984

J. Comparison To Predicate Devices

The proposed Weck® Metal Ligating Clips have the same technology and functional characteristics as the predicate system. The proposed modifications include the addition of magnetic resonance (MR Conditional) claims, addition of a contra-indication for renal donor nephrectomy, addition of cleaning and sterilization instructions for reusable instrumentation, two line extensions, a change in packaging materials, and a change in the sterilization method of the Horizon™ Ligating Clips.

K. Materials

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

L. Technological Characteristics

A comparison of the technological characteristics of the proposed Weck® Metal Ligating Clips and the predicates has been performed. The results of this comparison demonstrate that the Weck® Metal Ligating Clips are equivalent to the marketed predicate devices.

M. Performance Data

Non-clinical performance testing was conducted to support the "MR Conditional" labeling claim in accordance with ASTM F2503-08, *Standard Practice for Marketing Medical Devices and Other Items for Safety in the Magnetic Resonance Environment* as well as the FDA guidance document, *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment,* dated August 21, 2008. The results of these tests demonstrate that the Weck® Ligating Clips are "MR Conditional" and may be safely used in environments of 3-Tesla or less.

N. Conclusion

Based upon the comparative test results, the proposed Weck® Metal Ligating Clips are substantially equivalent in performance to the predicate devices cleared to market via 510(k) K982313 and K841547. The modifications made to the proposed Weck® Metal Ligating Clips do not introduce any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Teleflex Medical Incorporated
Ms. Ashlea Ricci, RAC
Senior Regulatory Affairs Specialist
2917 Weck Drive
Research Triangle Park, North Carolina 27709

November 27, 2013

Re: K132658
Trade/Device Name: Weck® Metal Ligation Clips
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: FZP
Dated: August 23, 2013
Received: August 30, 2013

Dear Ms. Ricci:

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 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,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K132658

Device Name: Weck® Metal Ligation Clips

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Prescription Use X (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)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K132658