510(k) SUMMARY

Hem-o-lok® Ligating Clips

DEC 3 0 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

November 8, 2013

D. Device Name

Trade Name:	Hem-o-lok® Ligating Clips
Common Name:	Implantable Clips
Classification Name:	Clips, Implantable
Product Code:	FZP

E. Device Description

Hem-o-lok® Ligating Clips are single-use, non-active implantable devices designed for use in general surgical procedures that require vessel or tissue ligation. The clips are available in four sizes (Medium, Medium-Large, Large, Extra Large), allowing the end user to ligate a wide range of vessels and tissue structures. Hem-o-lok® Ligating Clips are manufactured from a non-absorbable acetyl polymer and are provided prepackaged in color-coded cartridges, which are provided as single-use, sterile devices.

Accessories to the Hem-o-lok® 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

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Hem-o-lok® Ligating Clips are intended for use in procedures involving ligation of vessels or tissue structures. Surgeons should apply the appropriate size clip for the size of the vessel or tissue structure to be ligated such that the clip completely encompasses the vessel or tissue structure.

G. Contraindications

Hem-o-lok® Ligating Clips are not intended for use as a contraceptive tubal occlusion device.

Hem-o-lok® Ligating Clips are contraindicated for use in ligating the renal artery during laparoscopic donor nephrectomies.

H. Environmental Conditions

Hem-o-lok® Ligating Clips are "MR Safe" and pose no known hazards in MR environments.

I. Substantial Equivalence

The proposed Hem-o-lok® Ligating Clips are substantially equivalent to the predicate devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Hem-o-lok® Ligating Clips	Teleflex Medical (Weck)	K062914	11/2/2006
Hem-o-lok® Ligating Clips	Teleflex Medical (Weck)	K030311	2/6/2003

J. Comparison To Predicate Devices

The proposed Hem-o-lok® Ligating Clips have the same technology and functional characteristics as the predicate systems. The proposed modifications include the addition of magnetic resonance (MR Safe) claims, addition of cleaning and sterilization instructions for reusable instrumentation, the addition of a three-clip configuration, and a change in packaging materials.

K. Materials

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

L. Technological Characteristics

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

M. Performance Data

Non-clinical performance testing has been conducted in accordance with ISO 11607-1:2006, *Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems* in order to support changes to the materials used to package the Hem-o-lok® Ligating Clips. In addition, cleaning and sterilization validations were performed to assess manual and automated cleaning processes as well as pre-vacuum and gravity steam sterilization processes for Hem-o-lok® manual, reusable clip appliers and removers.

N. Conclusion

Based upon the comparative test results, the proposed Hem-o-lok® Ligating Clips are substantially equivalent in performance to the predicate devices cleared to market via 510(k) K062914 and K030311. The modifications made to the proposed Hem-o-lok® 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 20993-002

December 30, 2013

Teleflex Medical Incorporated
Ashlea Ricci, RAC
2917 Weck Drive
Research Triangle Park, North Carolina 27709

Re: K133202
Trade/Device Name: Hem-o-lok® Ligating Clips
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: FZP
Dated: October 11, 2013
Received: November 04, 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Binita S. Ashar -S
2013.12.30 15:34:33 -05'00'

Binita Ashar, MD, MBA, FACS
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K133202

Device Name: Hem-o-lok® Ligating Clips

Indications for Use:

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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: K133202