K062914

1/1

Teleflex
MEDICAL

Teleflex Medical Group Headquarters
2345 Waukegan Road
Bannockburn, IL 60015 USA
Phone: 847-572-8002
Fax: 847-572-8001
www.teleflex.com

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Hem-o-Lok® Ligating Clips

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

Teleflex Medical
2345 Waukegan Road
Suite 120
Bannockburn, IL 60015

NOV - 2 2006

B. Contact Person

Lori Hays
Senior Manager Regulatory Affairs

C. Date Prepared

September 21, 2006

D. Device Name

Trade Name: Hem-o-Lok® Ligating Clip
Common Name: Ligating Clip
Classification Name: Implantable Clip
Product Code: FZP
Regulation Number: 21 CFR 878.4300
Class: II

E. Device Description

The Weck Hem-o-Lok® ligation clip is a manually applied hemostatic clip intended to connect internal tissues to aid healing. The clips are intended for use in procedures involving ligation of vessels or tissue structures.

The Hem-o-Lok® clips are made from a non-absorbable acetyl polymer and are available in various sizes. Surgeons select 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.

F. Intended Use

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. Substantial Equivalence

The Weck Hem-o-Lok® ligating clips are substantially equivalent to the The Weck Hem-o-Lok® clips previously cleared under 510(k)s: K982941, K993157, K003337, K030311. and the Hem-o-Lok® ML Automatic Endoscopic Applier cleared under 510(k) K021808.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Teleflex Medical Group
% Ms. Lori Hays, MT, RAC
Senior Manager, Regulatory Affairs
2345 Waukegan Road
Bannockbun, Illinois 60015

NOV - 2 2006

Re: K062914
Trade/Device Name: Hem-o-Lok® Ligating Clip
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: FZP
Dated: September 21, 2006
Received: September 27, 2006

Dear Ms. Hays:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062914

Indications for Use

510(k) Number (if known):

Device Name: Hem-o-Lok® Ligating Clip

Indications For Use:

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.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062914