K030311

SUMMARY OF SAFETY AND EFFECTIVENESS

Pursuant to §513(i)(3)(A) of the Food, Drug, and cosmetic Act, Weck submits this summary of safety and effectiveness.

1. Submitter Name, Address, and Date of Submission

FEB 2 6 2003

Brian Young
Sr. Regulatory Affairs Manager
Weck Closure Systems
One Weck Drive
Research Triangle Park, NC 27709
Telephone: (919) 361-4041
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Submitted: January 29, 2003

2. Name of the Device, Common, Proprietary (if known), and Classification

Classification Name:	Implantable clip
Common Name:	Ligating clip
Proprietary Name:	Hem-O-Lok® Ligating Clip
Classification:	Class II, 21CFR §878.4300

3. Identification of the legally marketed device to which the submitter claims equivalence

The XL size clip described in this submission is substantially equivalent to previously cleared Weck Hem-o-lok® clip sizes.

4. Description of the Device

The Weck Hem-O-Lok™ ligation clip is a manually applied hemostatic clip intended to connect internal tissues to aid healing. Hem-o-Lok™ causes hemostasis through vessel ligation. The modified XL size clip is a larger version of the existing Hem-o-lok clip.

5. Intended Use of the Device

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.

6. Summary of Technological Characteristics

The technological characteristics are the same as or equivalent to the predicate device. The dimensional specification change does not adversely affect safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 6 2003

Mr. Brian Young
Senior Regulatory Affairs Manager
Weck Closure Systems
One Weck Drive
Research Triangle Park, North Carolina 27709

Re: K030311
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: January 29, 2003
Received: January 30, 2003

Dear Mr. Young:

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 (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K030311

Statement of Indications For Use

510(k) Number (if known): New Application

Device Name: Hem-o-lok™ Ligating Clip

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.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
Use
(Per 21 CRF 801.109)

OR

Over-The-Counter

(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030311