AUG 1 4 2002

K021808

PART 9
SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) SUMMARY

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

Brian Young
Sr. Regulatory Affairs Manager
Weck Closure Systems
One Weck Drive
Research Triangle Park, NC 27709
Telephone: (919) 361-4041
Facsimile: (919) 361-3914
Prepared: May 13, 2002

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

Classification Name:	Implantable clip
Common Name:	Ligating clip
Proprietary Name:	Weck Hem-o-Lok® Automatic Ligating Clip Applier

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

The clips delivered by the proposed automatic applier described in this submission are substantially equivalent to Weck Hem-o-lok® clips. The delivery mechanism is substantially equivalent to the U.S.S.C. AutoSuture® Endoclip 5mm Disposable Clip Applier, and Weck reusable ligating clip appliers.

4. Description of the Device

The Weck device is a sterile, single use, automatic ligating clip applier consisting of a handle, shaft containing 15 Hem-o-lok® locking polymer clips, and jaw. The major functions of the device are clip feeding, approximation (positioning the clip around the vessel), and closure. The applier is discarded after the surgical procedure whereas the applied non-absorbable polymer clips remain in the patient. Two models are offered: endoscopic and open surgery.

5. Intended Use of the Device

Weck Hem-o-lok Automatic Ligating Clip Appliers are indicated for use as delivery devices for Hem-o-lok non-absorbable polymer ligating clips. 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 structures to be ligated such that the clip completely encompasses the vessel or tissue structure.

6. Summary of Technological Characteristics

The technological characteristics are equivalent to the predicate devices. The results of bench and animal testing demonstrate that any differences between the new device and its predicates do not adversely affect performance or safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 4 2002

Weck
James Lucky
Vice-President, Regulatory Affairs and Quality Assurance
2917 Weck Drive
Durham, North Carolina 27709

Re: K021808
Trade/Device Name: Hem-o-Lok™ Automatic Ligating Clip Applier
Regulation Number: 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: FZP
Dated: May 31, 2002
Received: June 3, 2002

Dear Mr. Lucky:

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.

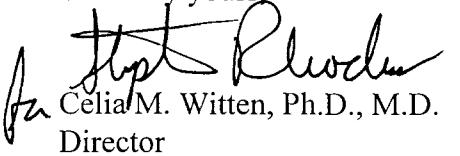
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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" (21 CFR Part 807.97). 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,



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

K021808

PART 7
INDICATION FOR USE

Statement of Indications For Use

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

Device Name: Hem-o-lok™ Automatic Ligating Clip Appliers

Weck Hem-o-lok Automatic Ligating Clip Appliers are indicated for use as delivery devices for Hem-o-lok non-absorbable polymer ligating clips. 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 structures to be ligated such that the clip completely encompasses the vessel or tissue structure.

* Note: The indications section of the labeling for the endoscopic model will refer to endoscopic use.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CRF 801.109)

OR

Over-The-Counter Use
(Optional Format 1-2-96)

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

510(k) Number K021808