NOV 19 1998

WECK CLOSURE SYSTEMS

K982941

Premarket Notification [510(k)] Summary for Small Hem-O-Lok® Ligation Clips

1. **Submitter Name, Address, and Date of Submission**

Mr. Brian J. Young
Regulatory Affairs Manager
Weck Closure Systems
One Weck Drive
Research Triangle Park, NC 27709

Telephone: (919) 361-4041
Facsimile: (919) 361-3914

Submitted: July 24, 1998

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

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

The Weck Closure Systems Hem-O-Lok® clip is substantially equivalent to Hem-O-Lok® clips cleared under Bristol Myers' 510(k) number K922186.

4. **Description of the Device**

Weck Closure System's 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 clip is nonabsorbable and is manufactured from polyacetal.

The clips are housed in a cartridge and packaged in a rigid plastic blister with Tyvek coated lidding which is sold sterile. The method of sterilization will be EtO with a SAL of 10^{-6}. The blister packs are fitted into an overpack carton which serves as the sales unit.

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 match clip size to the size of the vessel or tissue structure to be ligated.

6. Summary of Technological Characteristics

The technological characteristics are the same as or equivalent to the predicate device. The polyacetal material used in the clips is shown to be biocompatible.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K982941
Trade Name: Hem-O-Lok® Ligating clips
Regulatory Class: II
Product Code: FZP
Dated: July 30, 1998
Received: August 21, 1998

Dear Mr. Young:

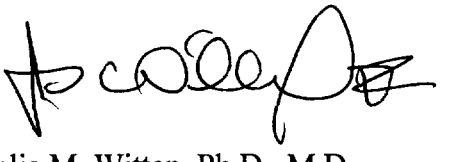
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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 and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K982941

2 Statement of indications for use

510(k) Number (if assigned): K982941
Device Name: Hem-O-Lok® ligating clips

INDICATIONS FOR USE

Hem-O-Lok® ligating clips are intended for use in procedures involving ligation of vessels or tissue structures. Surgeons should match clip size to the size of the vessel or tissue structure to be ligated.

Concurrence of CDRH, Office of Device Evaluation (ODE)

X Prescription

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982941