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
Facsimile: (919) 361-3914
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

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

January 30, 2003

WECK
2917 WECK DRIVE
RESEARCH TRIANGLE PARK, NC 27709
ATTN: BRIAN YOUNG

510(k) Number: K030311
Received: 30-JAN-2003
Product: HEM-O-LOK XL CLIP

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

As a reminder, we would like to mention that FDA requires all 510(k) submitters to provide an indications for use statement on a separate page. If you have not included this indications for use statement in addition to your 510(k) summary (807.92), or a 510(k) statement (807.93), and your Truthful and Accurate statement, please do so as soon as possible. If the above mentioned requirements have been submitted, please do not submit them again. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the DMC will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation
Center for Devices and Radiological Health

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Weck Closure Systems
2917 Weck Drive
Research Triangle Park, NC 27513

Special 510(k): Device Modification
For
Hem-o-lok® Ligating Clips

January 29, 2003

WECK®
A Teleflex Company

January 29, 2003

510(K) Document Mail Center (HFZ 401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

2003 JAN 30 A 11:42

Subject: Special 510(k) - Device Modification (change in dimensions) to the Hem-o-lok® Ligating Clip, K003337

Dear Sir/Madam:

According to the Food and Drug Administration Modernization Act of 1997 (FDAMA), Weck Closure Systems (Weck) submits this Special 510(k): Device Modification to introduce into commercial distribution a larger Hem-o-lok XL size Ligating Clip. The larger clip is the same as the existing clip sizes with respect to: (1) geometric shape; (2) material; (3) function; (4) packaging; (5) sterilization method & SAL; (6) application method; and (7) indications for use. **The clip is being changed only with respect to dimensional specifications. The modified clip has the same intended use and same fundamental scientific technology as the predicate (unmodified) device.**

The Hem-o-lok clip that is about to be modified received marketing clearance under: **K902108** (Original submission, medium size clips); **K922186** (addition of small and large size clips); **K941972** (change in ownership); **K982941 and K982944** (change in materials and labeling); **K993157** (change to indications and contraindications); and **K003337** (promotion for specific operating procedures).

The proposed change in dimensions was discussed with (b) (4), (b) (6) ODE/DGRND on November 14, 2001 via a telephone conference (b) (4), (b) (6) contacted because he is familiar with the Hem-o-lok ligating clip as a result of his review of prior Hem-o-lok 510(k) submissions. It was agreed that the Food and Drug Administration (FDA) could be notified of this change in dimensions by way of a Special 510(k) because the modified device has the same intended use and same fundamental scientific technology as the predicate (unmodified) device.

A "Declaration of Conformity" with design control requirements is included along with other content requirements specified in the March, 1998 FDA guidance "The new 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications".

SK 12

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Thank you in advance for your consideration of our application. Should you have any questions, please contact me at **919.361.4041.**

Sincerely,

Brian Young
Senior Regulatory Affairs Manager

Table of Contents

PART 1
GENERAL INFORMATION

CDRH SUBMISSION COVER SHEET

Date of Submission: **FDA Document Number:**

Section A **Type of Submission**

PMA	PMA Supplement	PDP	510(k)	Meeting
Original Submission ☐ Modular Submission ☐ Amendment ☐ Report ☐ Report Amendment	☐ Regular ☐ Special ☐ Panel Track ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA Supplement	☐ Presubmission Summary ☐ Original PDP ☐ Notice of intent to start clinical trials ☐ Intention to submit Notice of Completion ☐ Notice of Completion ☐ Amendment to PDP ☐ Report	× Original Submission: ☐ Traditional ☒ Special ☐ Abbreviated ☐ Additional Information: ☐ Traditional × Special ☐ Abbreviated ☐ Report Amendment	☐ Pre-IDE mtg. ☐ Pre-PMA mtg. ☐ Pre-PDP mtg. ☐ 180-Day mtg. ☐ Other (specify):
IDE	**Humanitarian Device Exemption**	**Class II Exemption**	**Evaluation of Automatic Class III Designation**	**Other Submission**
☐ Original submission ☐ Amendment ☐ Supplement	☐ Original submission ☐ Amendment ☐ Supplement ☐ Report	☐ Original Submission ☐ Additional Information	☐ Original Submission ☐ Additional Information	Describe Submission:

Section B **Applicant or Sponsor**

Company/Institution Name: **Weck**		Establishment registration number: (b) (4)	
Division Name (if applicable): **N/A**		Phone number (include area code): **919.361-4041**	
Street Address: **2917 Weck Drive**		Fax number (include area code): **919.361.3914**	
City: **Research Triangle Park**	State/Province: **NC**	Zip code: **27709**	Country: **U.S.A.**
Contact Name: **Brian Young**			
Contact Title: **Sr. Regulatory Manager**		Contact e-mail address: **byoung@wecksurgical.com**	

Section C **Submission Correspondent (if different from above)**

Company/Institution Name:		Establishment registration number:	
Division name (if applicable)		Phone number (include area code):	
Street Address:		Fax number (include area code):	
City:	State/Province:	Zip Code:	Country
Contact Name:			

PART 1
GENERAL INFORMATION

Section D1 **Reason for Submission – PMA,PDP, or HDE**

☐ New Device
☐ Withdrawal
☐ Additional or Expanded Indications
☐ Licensing Agreement

☐ Change in design, component, or specification:
- ☐ Software
- ☐ Color Additive
- ☐ Material
- ☐ Specifications
- ☐ Other (specify below)

☐ Location Change:
- ☐ Manufacturer
- ☐ Sterilizer
- ☐ Packager
- ☐ Distributor

☐ Processing Change:
- ☐ Manufacturing
- ☐ Sterilization
- ☐ Packaging
- ☐ Other (specify below)

☐ Labeling Change:
- ☐ Indications
- ☐ Instructions
- ☐ Performance Characteristics
- ☐ Shelf Life
- ☐ Trade Name
- ☐ Other (specify below)_

☐ Report Submission:
- ☐ Annual or Periodic
- ☐ Post Approval Study
- ☐ Adverse Reaction
- ☐ Device Defect
- ☐ Amendment

☐ Response to FDA correspondence:
- ☐ Request for applicant hold
- ☐ Request for removal of applicant hold
- ☐ Request for extension
- ☐ Request to remove or add manufacturing site

☐ Change in Ownership
☐ Change in correspondent

☐ Other Reason (specify):

Section D2 **Reason for Submission - IDE**

☐ New device
☐ Addition of institution
☐ Expansion/extension of study
☐ IRB certification
☐ Request hearing
☐ Request waiver
☐ Termination of study
☐ Withdrawal of application
☐ Unanticipated adverse effect
☐ Notification of emergency use
☐ Compassionate use request
☐ Treatment IDE
☐ Continuing availability request

Change in:
- ☐ Correspondent
- ☐ Design
- ☐ Informed consent
- ☐ Manufacturer
- ☐ Manufacturing process
- ☐ Protocol – feasibility
- ☐ Protocol – other
- ☐ Sponsor

☐ Report Submission:
- ☐ Current investigator
- ☐ Annual progress
- ☐ Site waiver limit reached
- ☐ Final

☐ Response to FDA letter concerning:
- ☐ Conditional approval
- ☐ Deemed approval
- ☐ Deficient final report
- ☐ Deficient progress report
- ☐ Deficient investigator report
- ☐ Disapproval
- ☐ Request extension for time to respond to FDA
- ☐ Request meeting

☐ Other reason (specify):

Section D3 **Reason for Submission – 510(k)**

☐ New Device
☐ Additional or expanded indications
☐ Change in technology
× Change in design
☐ Change in materials
☐ Change in manufacturing process
☐ Other reason (specify): **Change in dimensional specifications related to introduction of a larger size clip.**

PART 1
GENERAL INFORMATION

Section E	Additional Information on 510(k) Submissions			
Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning safety and effectiveness data: ×510(k) summary attached ☐510(k) statement
1 79FZP	2	3	4	
5	6	7	8	

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade of Proprietary or model name	Manufacturer
1 K003337	1 Hem-o-lok Ligating Clips	1 Weck Closure Systems
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6

Section F	Product Information – Applicable to All Applications
Common or usual name or classification name: **Implantable clip**	

Trade or proprietary or model name	Model Number
1 Hem-o-lok XL Clip	1 544250
2	2
3	3
4	4
5	5

FDA document numbers of all prior related submissions (regardless of outcome):

1 K902108	2 K922186	3 K941972	4 K982941	5 K982941	6 K993157

Data included in submission: ☐Laboratory Testing ☐Animal Trials ☐Human Trials

Section G	Product Classification – Applicable to All Applicants	
Product code: 79FZP	C.F.R. Section: 21CFR 878.4300	Device Class: ☐Class I × Class II ☐Class III ☐Unclassified
Classification Panel: General and Restorative Devices (DGRND)		

Indications (from labeling): **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.**

PART 1
GENERAL INFORMATION

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.			FDA Document Number:
Section H	**Manufacturing/Packaging/Sterilization Sites Relating to a Submission**		
× Original ☐ Add ☐ Delete	FDA establishment registration number: (b) (4)	× Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager/relabeler
Company/Institution name: **Weck**		Establishment registration number: **1044475**	
Division name (if applicable): **N/A**		Phone number (include area code): **(919) 361-4041**	
Street address: **2917 Weck Drive**		FAX number (include area code): **(919) 361-3914**	
City **Research Triangle Park**	State/Province: **NC**	Zip code: **27709**	Country: **U.S.A.**
Contact name: **Brian Young**			
Contact title: **Sr. Regulatory Affairs Manager**			
× Original ☐ Add ☐ Delete	FDA Establishment registration number: (b) (4)	☐ Manufacturer ☐ Contract Manufacturer	× Contract Sterilizer ☐ Repackager/relabeler

(b) (4)

☐ Original ☐ Add ☐ Delete	FDA Establishment registration number:	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract sterilizer ☐ Repackager/relabeler
Company/Institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code):	
Street address:		FAX number (include area code):	
City:	State/Province:	Zip code:	Country:
Contact name:			
Contact title:	Contact e-mail address:		

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PART 2
DEVICE DESCRIPTION AND COMPARISON

1. INTRODUCTION

Weck'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.

Weck manufactures and distributes clip appliers for endoscopic and open surgical application of Hem-o-lok clips. The appliers are Class I reusable stainless steel devices, reference 21 CFR §878.4800.

2. GENERAL DEVICE CHARACTERISTICS

The modified device is (b) (4) version of the existing Hem-o-lok MLX size clip. The size relationship of the modified XL clip in relationship to the current FDA cleared clip sizes is illustrated in **Figure 1**.

Figure 1 – Illustration of the size of the new XL clip

Existing Unmodified Sizes New Modified Size

3. COMPONENTS AND MATERIALS

a) Clip

The clip is nonabsorbable and is manufactured from (b) (4) The same (b) (4) will be used to mold the XL size clip as has been used for the

existing FDA cleared clip sizes. Biocompatibility testing of the clip was included in 510(k) numbers **K982941 and K982944** and is therefore not included herein.

b) Packaging

The same packaging materials and concept will be used for the new XL sized clip as has been used for the existing FDA cleared clip sizes. The sterile unit package consists of a heat-sealed rigid (b) (4) blister with a heat sealed Tyvek (b) (4) lid. The blister packs are fitted into an overpack carton which serves as the sales unit.

c) Sterilization

The method of sterilization is EtO to an SAL of 10^{-6}. Sterilization is performed at our contract sterilizer IBA using validated methods.

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PART 3
Substantial Equivalence

1. Legally Marketed Predicate Device

The legally marketed (unmodified) Hem-o-lok device received marketing clearance under: **K902108** (Original submission, medium size clips); **K922186** (addition of small and large size clips); **K941972** (change in ownership); **K982941 and K982944** (change in materials and labeling); **K993157** (change to indications and contraindications); and **K003337** (promotion for specific operating procedures).

2. Substantial Equivalence

The modified XL size clip has the following similarities to the predicate (unmodified) Hem-o-lok clips:

- The same indicated use;
- The same instructions, cautions, and warnings;
- The same clip material;
- The same geometric shape and function;
- The same packaging concept;
- The same sterilization process; and
- The same means of application.

In summary, the Hem-o-lok XL size clip described in this submission is, in our opinion, substantially equivalent to the predicate (unmodified) Hem-o-lok clip.

PART 4
DEVICE INTENDED USE

The new XL size clip has the same intended use as the previously cleared clip sizes: to effectuate hemostasis by vessel ligation. The new XL size clip will have exactly the same indications for use as the existing FDA cleared Hem-o-lok clips, reference **K003337**:

> 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.

The indication for use statement is provided herein.

PART 5
DESIGN CONTROL ACTIVITIES

1. Risk Analysis Method

The risk analysis method used to assess the impact of the modification was a Failure Modes and Effects Analysis (FMEA) conducted pursuant to Weck's risk analysis

(b) (4) [redacted]

2. Design Verification Testing

The design verification tests that were performed as a result of this risk assessment are listed in **Table 1** below.

Table 1 – Verification Tests

(b) (4) [redacted]

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(b) (4)

A declaration of conformity with design controls is included on the next page.

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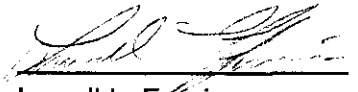
PART 6
DECLARATION OF CONFORMITY

1. Declaration of Conformity with Design Controls

To the best of my knowledge, the verification activities, as required by the risk analysis, for the Hem-o-lok XL clip modification were performed by the designated individuals and the results demonstrated that the predetermined acceptance criteria were met.



Lowell LaFreniere
V.P., Product Development
WECK a Teleflex Company

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PART 6
DECLARATION OF CONFORMITY

2. Manufacturing Facility Conformance Statement

The manufacturing facility, Weck is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.

1-27-05

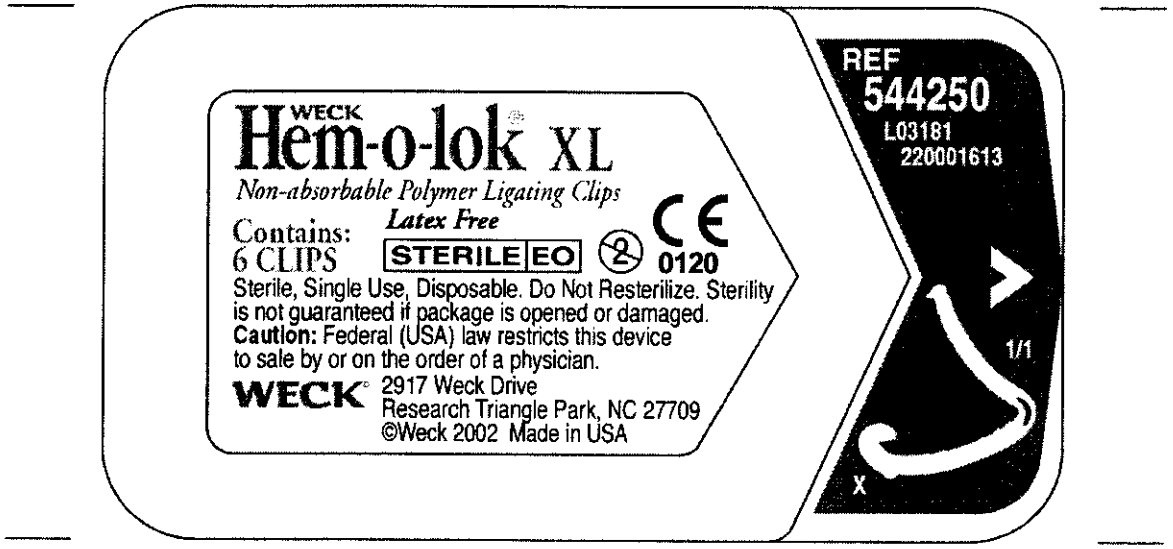
James L. Lucky
V.P., Regulatory Affairs and Quality Assurance
WECK a Teleflex Company

PART 7
DEVICE LABELING

DEVICE LABELING:
(Modified Device)

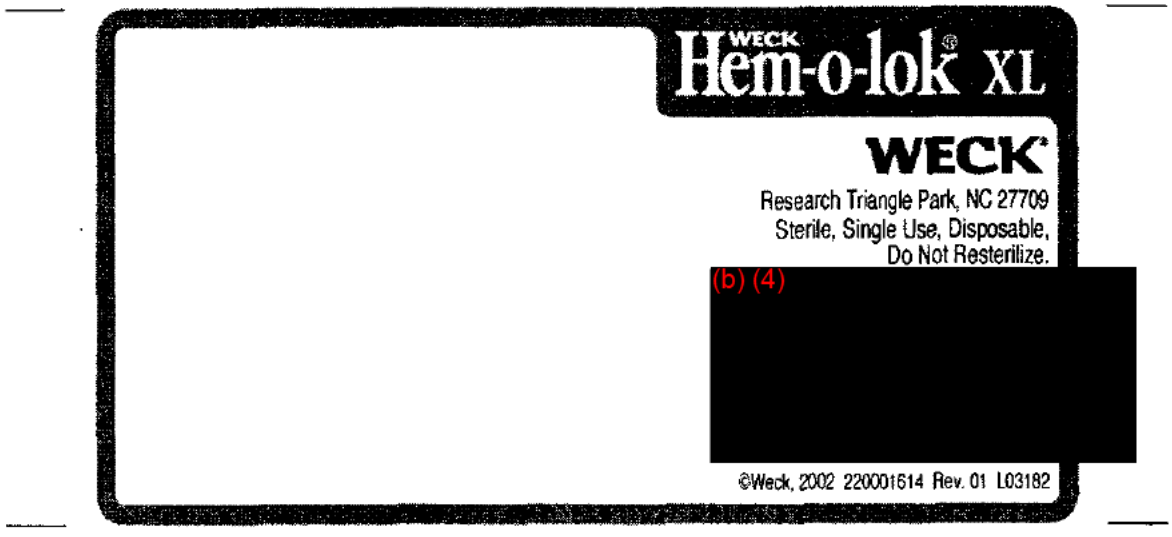
45

Sterile unit label (Modified device)



*Note: The lot number will be printed in line on the blister.

Sales unit label stock (new)
(applied to generic Hem-o-lok box)



The following information is printed in-line on the above label stock:

- Catalog number (REF);
- Lot number (LOT);
- Manufacturing date (MFG);
- The description: Non-absorbable Polymer Ligation Clips;
- The net quantity of contents: 14 Packages, 6 Clips per Package;
- Sterile, EO; and
- Bar codes.

English

Hem-o-lok®

Hem-o-lok Clip Applier and Hem-o-lok Non-absorbable Polymer Ligating Clips

INDICATIONS

Weck® Hem-o-lok® Ligating Clip Appliers are indicated for use as delivery devices for Hem-o-lok Non-absorbable Polymer Ligating Clips. Other ligating clips cannot be used with these appliers.

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.

CONTRAINDICATIONS

This product is not intended for use as a contraceptive tubal occlusion device.

PRECAUTION

The clip must be latched to ensure proper ligation of the vessel or tissue. Inspect the ligation site after application to ensure proper closure. Weck recommends ligation of the renal artery with two (2) clips on the patient side in a nephrectomy. Application of a second clip on all other vessels should be dictated by the surgeon's judgement in all other cases. The Hem-o-lok Polymer Ligating Clip is not designed for use as a tissue marker.

CAUTION

Always check the alignment of the applier jaws before use. If this is not done, patient injury may occur. Before applying a clip, verify the structural size and condition of the vessel or structure and use the proper clip size. It is the responsibility of the user to select structures for the application of clips and confirm secure grip of the clips after placement, and after the use of other surgical devices in the immediate area of the application. **NOTE: Hem-o-lok ligating clips are supplied sterile. DO NOT resterilize ligating clip cartridges.**

CARE, CLEANING, AND STERILIZATION

Manual-load applier jaws are delicate and can easily become damaged. Mishandling of appliers may result in improper load and/or closure of the ligating clips. Appropriate care, cleaning and maintenance are important to ensure proper function.

All Weck ring-handled manual load reusable ligating clip appliers are supplied nonsterile. The instrument should be cleaned and sterilized prior to each use. Clean the instrument before sterilization and in the same manner as any reusable instrument and in accordance with hospital practice. **A pre-vacuum steam cycle of 4 minutes at 270-275°F is recommended for safe, effective sterilization. Sterilization cycles other than those recommended by Weck should be validated using appropriate laboratory methods.**

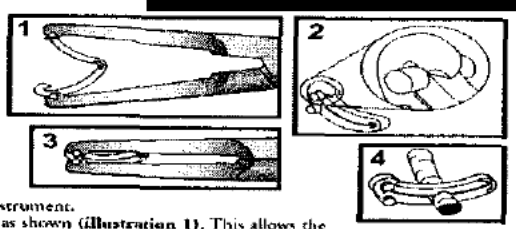
INSTRUCTIONS FOR USE

Hem-o-lok ligating clips are generally suited to vessel and tissue structure sizes indicated in the accompanying chart. Surgeon judgement should dictate clip selection for specific applications.

[redacted] (b) (4)

Loading clips

1. To load the applier, grasp the applier and carefully insert the jaws of the applier into the cartridge slot, making sure the jaws are perpendicular to the base of the cartridge. Gently press the applier over the clip until there is an audible click. Do not force the applier into the cartridge or onto the clip. The applier should enter and withdraw from the cartridge easily.
2. Remove the applier from the cartridge ensuring the clip is held securely in the applier jaws **(illustration 1)**. It may be necessary to hold the cartridge to allow the clip to be removed.



Clip positioning and closure

3. Sufficiently skeletonize the structure to be ligated to allow the locking mechanism of the clip to be clear of tissue. Do not use the clip or applier as a dissecting instrument.
4. During application, orient the single tooth of the clip as shown **(illustration 1)**. This allows the user to visually confirm encapsulation of the structure being ligated.
5. Position the clip around the tissue to be ligated in a manner that provides clear visualization of the locking mechanism **(illustration 2)**. Apply sufficient force to the applier handles so the jaws close and the clip locks shut **(illustration 3)**. Releasing pressure on the applier handles allows the applier to return to a fully open position. **NOTE: Leave a distal cuff of tissue approximately 1-2mm from the ligating clip if the tissue is to be divided (illustration 4), i.e. do not use the side of the clip as a cutting guide.**
6. Withdraw the applier from the ligation site.

LIGATING SYSTEM COMPATIBILITY

There are a number of ligating clips on the market today in addition to Hem-o-lok ligating clips from Weck. Your Weck Hem-o-lok applier has been designed for use exclusively with Hem-o-lok Ligating Clips. Applier color coding matches the color of the ligating clip cartridge with which it is to be used. Weck does not assume responsibility for unsatisfactory results caused by the use of any equipment or clips not specifically identified by Weck as an integral part of this specific system.

CE 0120 EU Authorized Representative:
TFX Medical Ltd.
Stirling Road
High Wycombe HP12 3ST U.K.

STERILE EO Rx ONLY

CE
WECK
A Teleflex Company

Manufactured by: Weck Closure Systems, 2917 Weck Drive, Research Triangle Park, NC 27709 USA. USA: (800) 234-9325 • FAX (800) 932-5329. International: (919) 361-3961 • FAX (919) 361-4111. U.S. Patent No. 4,685,460 ©Weck Closure Systems, 2003 220001676 Rev. 00 L03207

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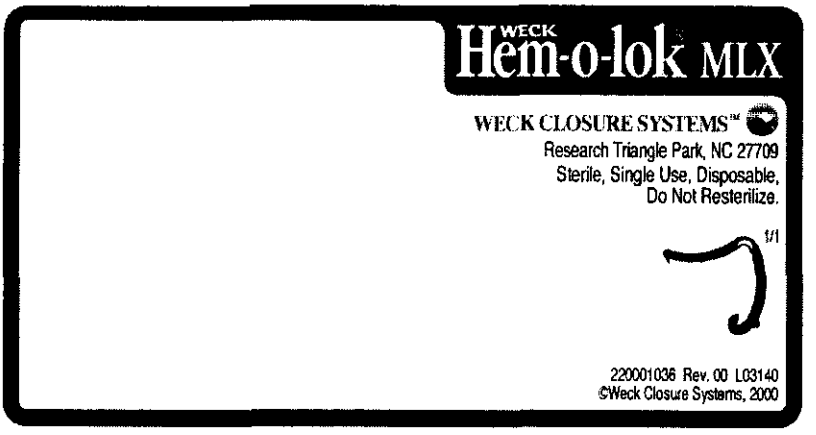
PART 7
DEVICE LABELING

Continued - Predicate Unmodified Device

(Sterile blister pack label)

*Note: The lot number will be printed in line on the blister.

Sales unit label stock
(applied to generic Hem-o-lok box – next label in series)



The following information is printed in-line on the above label stock:

- Catalog number (REF);
- Lot number (LOT);
- Manufacturing date (MFG);
- The description: Non-absorbable Polymer Ligation Clips;
- The net quantity of contents: 14 Packages, 6 Clips per Package;
- Sterile, EO; and
- Bar codes.

Generic Hem-o-lok Box
(label on previous page applied to differentiate each clip)

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INFORMATION BOOKLET · FICHE D'INFORMATION · INFORMATIONSBLATT · OPUSCOLO ILLUSTRATIVO · FICHA INFORMATIVA

WECK Hem-o-lok®

Hem-o-lok Clip Applier and Hem-o-lok Non-absorbable Polymer Ligating Clips

Applier Features: Opens Fully for Cleaning and Sterilization • Color Coded to Match Appropriate Clip Cartridge. **Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.

Pinces à clips Hem-o-lok et clips de ligature en polymère non résorbable.

Caractéristiques de l'applicateur: S'ouvre complètement pour le nettoyage et la stérilisation • Porte des codes couleur pour une meilleure identification cartouche/pince.

Hem-o-lok Clipanlegezangen und nicht absorbierbare Hem-o-lok Ligaturclips aus Polymer

Charakteristischen der Anlegezange: Kann zu Reinigungs- und Sterilisationszwecken vollständig geöffnet werden • Zueinandergehörige Clip-Magazine und Clipanlegezangen sind mit einem Farbencode versehen, der die Identifizierung erleichtert.

Pinze posa-clip da legatura Hem-o-lok e clips da legatura Hem-o-lok in polimero non riassorbibile

Caratteristiche della pinza posa clip: Si apre interamente per la pulizia e la sterilizzazione • Corredato da un codice a colori corrispondente al colore del caricatore di clip da utilizzare.

Pinzas aplicadoras de clips para ligaduras Hem-o-lok y clips para ligadura de polímero no absorbible Hem-o-lok

Características del aplicador: Se abre completamente para la limpieza y la esterilización • Lleva códigos de color para facilitar la identificación cartucho/pinza.

CE 0120 TFX Medical Ltd.
Stirling Road
High Wycombe HP12 3ST U.K.

STERILE EO

Sterilized by EtO. Single use. Disposable. Hem-o-lok ligating clip cartridges contain barium and are radiopaque. Read instructions for use. Store this booklet in a safe place!

Les cartouches de clips de ligature Hem-o-lok contiennent du barium et sont radio-opaques. Rangez cette brochure dans un endroit sûr.

Anmerkung: Hem-o-lok Ligaturclipmagazine enthalten Barium und sind für Röntgenstrahlen undurchlässig. Bewahren Sie diese Broschüre an einem sicheren Ort auf.

I caricatori delle clip per legatura Hem-o-lok contengono bario e sono radio-opachi. Conservare le presenti istruzioni in un luogo sicuro.

Los cartuchos de clips de ligadura Hem-o-lok contienen bario y son radioopacos. Guárdese este folleto en un lugar apropiado.

WECK CLOSURE SYSTEMS™

STERILE EO — Sterilized by EtO. Stérilisé à l'oxyde d'éthylène. Mit Ethylenoxid sterilisiert. Sterilizzato all'ossido di etilene. Esterilizado con óxido de etileno.

LOT — Lot number. Numéro du lot. Lotnummer. Numero di lotto. Lote N°.

REF — Catalog number. N° de référence. Artikelnummer. Codice articolo. Referencia N°.

Date of manufacture. Date de fabrication. Herstellungsdatum. Data di fabbricazione. Fecha de fabricación.

Use by. Utiliser avant. Verwendbar bis. Data di scadenza. Utilizar hasta.

Single use. Usage unique. Einmalprodukt. Monouso. De uso único.

Read instructions for use. Attention: Voir notice d'instructions. Achtung: Benutzunghinweise beachten. Attenzione: Vedere le istruzioni per l'uso. Precaución: Léanse las instrucciones antes de uso.

WECK CLOSURE SYSTEMS™

Manufactured by: · Fabriqué par: · Hergestellt von: · Fabbricato per · Fabricado por:
Weck Closure Systems, One Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 800 234-WECK, 919 544-8000 • Fax: 800 932-5329

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INDICATIONS

Weck Closure Systems™ Hem-o-lok® Ligating Clip Appliers are indicated for use as delivery devices for Hem-o-lok Non-absorbable Polymer Ligating Clips. Other ligating clips cannot be used with these appliers.

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.

CONTRAINDICATIONS

This product is not intended for use as a contraceptive tubal occlusion device.

PRECAUTION

The clip must be latched to ensure proper ligation of the vessel or tissue. Inspect the ligation site after application to ensure proper closure. The Hem-o-lok Polymer Ligating Clip is not designed for use as a tissue marker.

CAUTION

Always check the alignment of the applier jaws before use. If this is not done, patient injury may occur. Before applying a clip, verify the structural size and condition of the vessel or structure and use the proper clip size. It is the responsibility of the user to select structures for the application of clips and confirm secure grip of the clips after placement, and after the use of other surgical devices in the immediate area of the application.

NOTE: Hem-o-lok ligating clips are supplied sterile. DO NOT resterilize ligating clip cartridges.

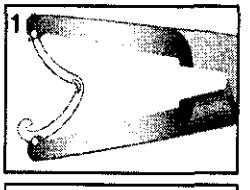
CARE, CLEANING, AND STERILIZATION

Manual-load applier jaws are delicate and can easily become damaged. Mishandling of appliers may result in improper load and/or closure of the ligating clips. Appropriate care, cleaning and maintenance are important to ensure proper function.

All Weck Closure Systems ring-handled manual load reusable ligating clip appliers are supplied nonsterile. The instrument should be cleaned and sterilized prior to each use. Clean the instrument before sterilization and in the same manner as any reusable instrument and in accordance with hospital practice. A pre-vacuum steam cycle of 4 minutes at 270-275°F is recommended for safe, effective sterilization. Sterilization cycles other than those recommended by Weck Closure Systems should be validated using appropriate laboratory methods.

INSTRUCTIONS FOR USE

1. To load the applier, grasp the applier and carefully insert the jaws of the applier into the cartridge slot, making sure the jaws are perpendicular to the base of the cartridge. Gently press the applier over the clip until there is an audible click. Do not force the applier into the cartridge or onto the clip. The applier should enter and withdraw from the cartridge easily.
2. Remove the applier from the cartridge ensuring the clip is held securely in the applier jaws **(illustration 1)**. It may be necessary to hold the cartridge to allow the clip to be removed.
3. Position the clip around the tissue to be ligated. Apply sufficient force to the applier handles so the jaws close and the clip locks shut **(illustration 2)**. Releasing pressure on the applier handles allows the applier to return to a fully open position. Withdraw the applier from the ligation site.



LIGATING SYSTEM COMPATIBILITY

There are a number of ligating clips on the market today in addition to Hem-o-lok ligating clips from Weck Closure Systems. Your Weck Closure Systems Hem-o-lok applier has been designed for use exclusively with Hem-o-lok Ligating Clips. Applier color coding matches the color of the ligating clip cartridge with which it is to be used. Weck Closure Systems does not assume responsibility for unsatisfactory results caused by the use of any equipment or clips not specifically identified by Weck Closure Systems as an integral part of this specific system.

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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 OR Over-The-Counter Use
(Per 21 CRF 801.109)

(Optional Format 1-2-96)

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PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As Required by 21CFR807.879j))

I certify that, in my capacity as Senior Regulatory Affairs Manager of Weck, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Brian Young, Sr. RA Manager

1-29-03
date

(510(k) number)

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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

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
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.

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 030311

Reviewer: [signature]

Division/Branch: DGRND/PRSB

Device Name: HEM-O-LOK XL CLIP

Product To Which Compared (510(K) Number If Known): K003337

	YES	NO	
1. Is Product A Device	✓		If NO = Stop
2. Is Device Subject To 510(k)?	✓		If NO = Stop
3. Same Indication Statement?	✓		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?		✓	If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?		✓	If YES = Go To 8
7. Descriptive Characteristics Precise Enough?	✓		If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: *In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.*

1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:
   Clip is 34% larger

6. Explain how new characteristics could or could not affect safety or effectiveness:
   34% increase ONLY translates to a 3 mm size increase in vessel created

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?	N.A.	
4. If, not, has POS been notified?	N.A.	
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?	N.A.	
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.	N.A.	

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To: THE FILE RE: DOCUMENT NUMBER K030311

DATE: 2/21/03

SUBJ: HEM-O-LOK XL Clip
Weck

Mr. Brian Young
2917 Weck Drive
Research Triangle Park, NC 27709

Recommendation: Substantially equivalent

Procode:	79 FZP
Class:	II
Regulation Number:	21 CFR 878.4300
Regulation Name:	Implantable Clip

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)
2. Submitter's statement that the INDICATION/INTENDED USE of the modified device as described in its labeling HAS NOT CHANGED along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials.
3. A description of the device MODIFICATION(S), including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the FUNDAMENTAL SCIENTIFIC TECHNOLOGY of the modified device has not changed.
   This change was for (b) (4) modified device (XL) (b) (4) The clip is nonabsorbable and is manufactured from (b) (4) – the same (b) (4) for the sponsor's other hemostatic clips cleared via K902108 and K922186. The (b) (4) clip size translates in to only (b) (4) The labeling reflects specifies that the modified clip is capable of clipping vessels (b) (4) . The previously cleared large clip is specified for vessel (b) (4) diameter.
4. Comparison Information (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and clip material, packaging and sterilization.
5. A Design Control Activities Summary which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
   The results were not included. On February 19th I called Mr. Brian Young and requested that he send the results of the risk analysis testing. In addition I requested that he provide the considerations with regard to (b) (4) test design. The information was received on February 20th. Dr. Herb Lerner provided consultative review regarding clinical concerns.

Dr. Lerner, Mr. Rhodes and I discussed the application on February 21. Review of previous submissions (K902108 – medium clip, K922186 – small and large clips) revealed the type of testing conducted prior to marketing clearance. For the medium size clip the sponsor conducted the following tests:

(b) (4) Testing

[redacted]

6. A Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure.

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The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

(Reviewer's Signature) 2/21/03 (Date)

Comments

Concur
MS 2/26/03

SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K030311

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

☑ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☐ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	N.A.	
Class III Certification and Summary. **	N.A.	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	N.A.	
510(k) Kit Certification ***	N.A.	

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.	✓	
A description of the modified device and a comparison to the sponsor's predicate device.	✓	
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.	✓	
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.	✓	
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.	✓	
c. A Declaration of Conformity with design controls that includes the following statements:	✓	
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.	✓	
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.	✓	

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, **SEE Required Elements for a Declaration of Conformity to a Recognized Standard,** which		

is posted with the 510(k) boilers on the H drive.]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, *in order to determine substantial equivalence.*		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the " Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening ✓ Yes ____ No
Reviewer: [signature]
Concurrence by Review Branch: [signature]

Date:

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

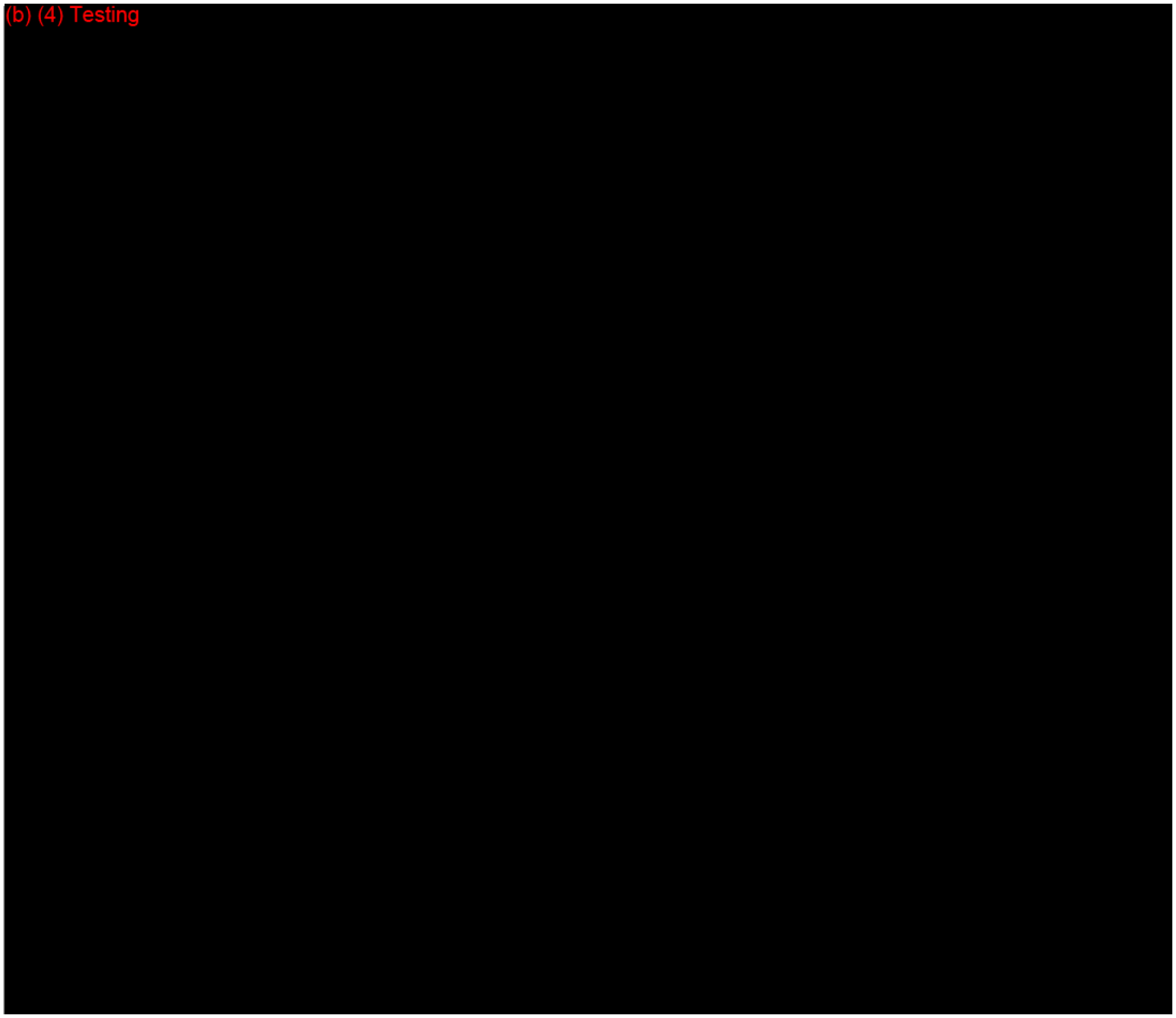
(b) (4) Testing

(b) (4) Testing

(b) (4) Testing

RESULTS:

(b) (4) Testing



(b) (4) Testing

(b) (4) Testing

(b) (4) Testing

(b) (4) Testing

(b) (4) Testing

(b) (4) Testing

(b) (4) Dimensions

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service
Food and Drug Administration

Feb. 24, 2003

Memorandum DXK

From: Reviewer(s) - Name(s) [signature]

Subject: 510(k) Number K030311

To: The Record - It is my recommendation that the subject 510(k) Notification:

☐ Refused to accept.

☐ Requires additional information (other than refuse to accept).

☒ Is substantially equivalent to marketed devices. K1 - SE

☐ NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? ☐ YES ☐ NO

☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☒ YES	☐ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☒ Enclosed
(required for originals received 3-14-95 and after)

☒ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☒ The indication for use form (required for originals received 1-1-96 and after)

Animal Tissue Source ☐ YES ☒ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 d

Predicate Product Code with class: 74 FEP 21 CFR 878.4300 Implantable Clip, Class II

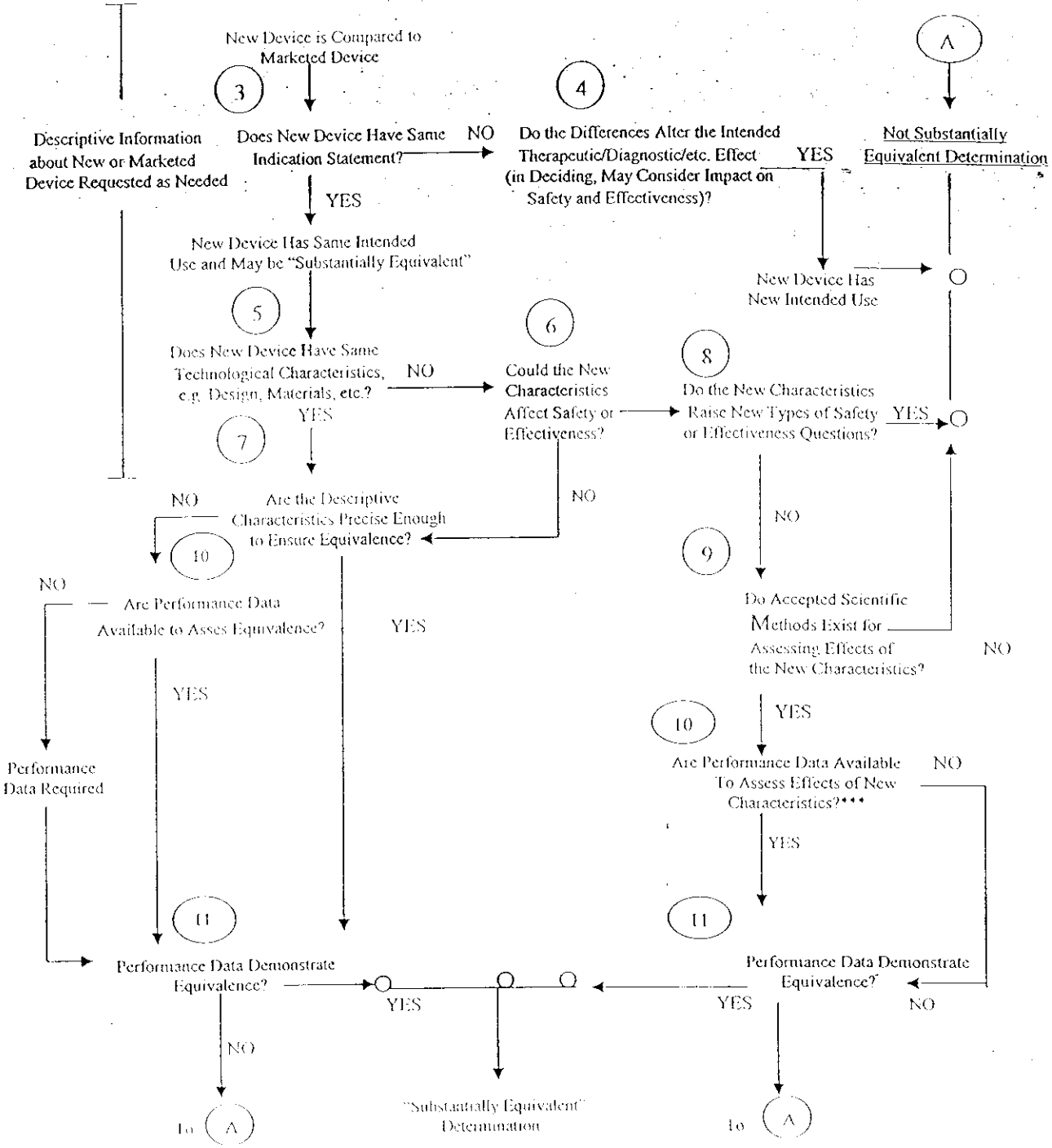
Additional Product Code(s) with panel (optional):

Review: [signature] Rhoda PRSB 2/24/03
(Branch Chief) (Branch Code) (Date)

Final Review: for Miriam C. Provost 2/26/03
(Division Director) (Date)

Revised 8/17/99

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature

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