NOV 19 1998 Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

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.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

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.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 1998

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.

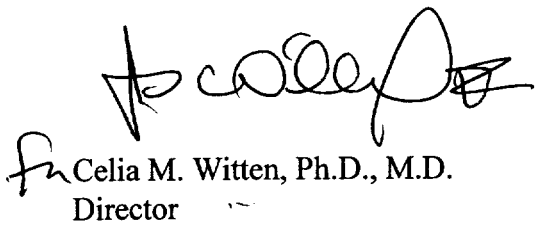
Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

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

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/2/2017

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

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

DEPARTMENT OF HEALTH & HUMAN SERVICES

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NOV 19 1998

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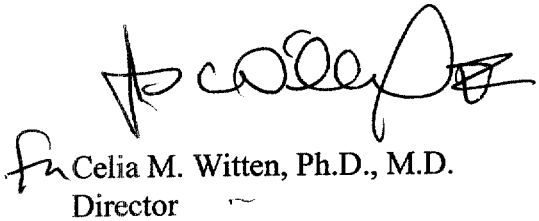

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Records Processed under FOI request 2017-6482; Released by CDRH on 10/02/2017

K982941

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

INDICATIONS FOR USE

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Concurrence of CDRH, Office of Device Evaluation (ODE)

X Prescription

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

3

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

om: Reviewer(s) - Name(s) [illegible]

Memorandum

ıbject: 510(k) Number K982941

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

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☐ Accepted for review _____.
- ☒ Is substantially equivalent to marketed devices. SE - K1
- ☐ 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
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)?	☐ 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)

laterial of Biological Origin ☐ YES ☒ NO

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

o Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: 79 FZP II Clip, Implantable

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

v: [illegible] (Branch Chief) SRA (Branch Code) 11/13/98 (Date)

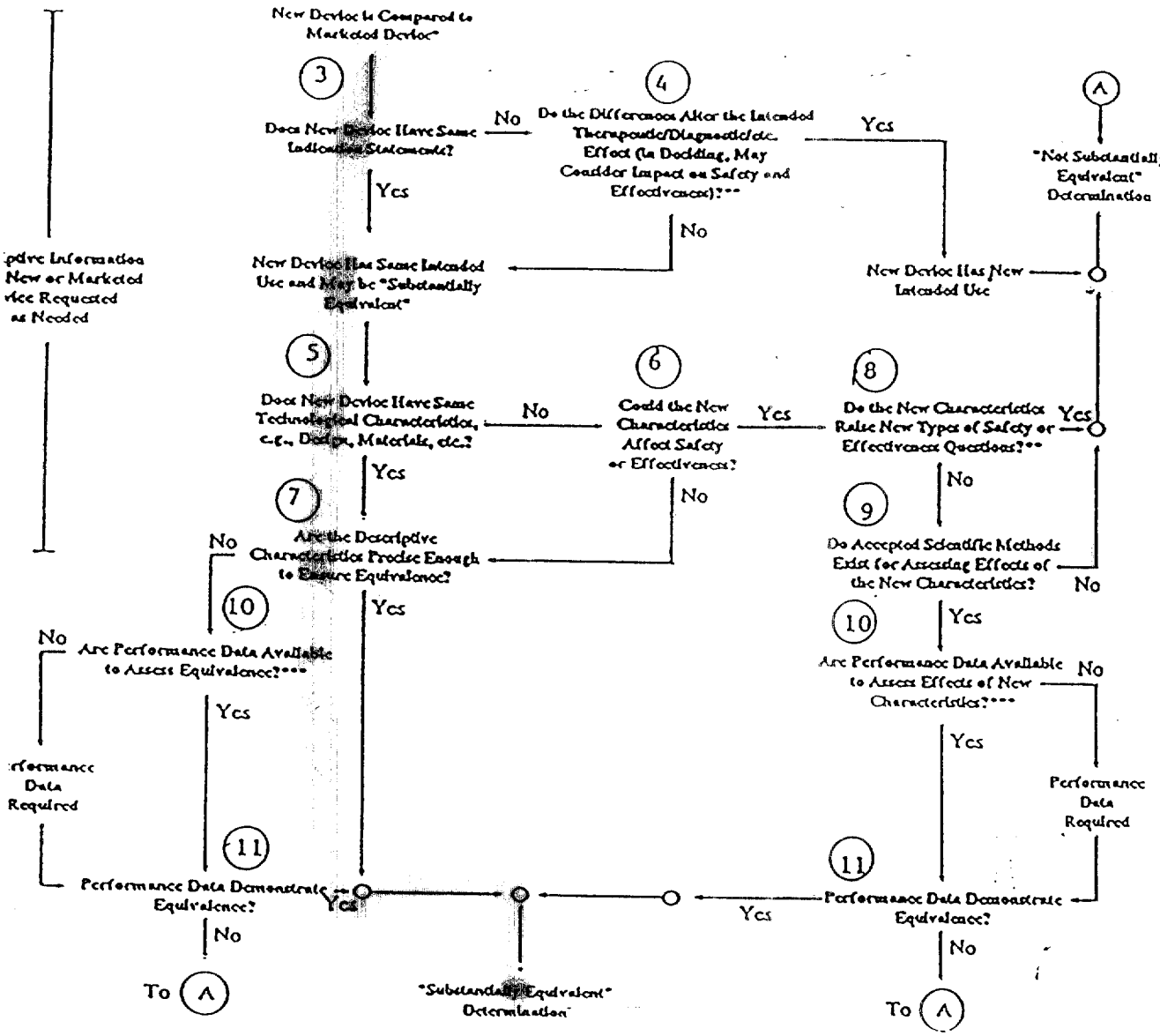
eview: [illegible] (Division Director) 11/16/98 (Date)

*Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

6/2/98

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

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



10(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship etween marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

his decision is normally based on descriptive information alone, but limited testing information is sometimes required.

ata may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

5

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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 982941

Reviewer: C L Hudson

Division/Branch: DGRD/PRSB

Device Name: HEM-O-LOK Model #4 523900, 523970

Product To Which Compared (510(K) Number If Known): K922186

	YES	NO	
1. Is Product A Device	X		If **NO** = Stop
2. Is Device Subject To 510(k)?	X		If **NO** = Stop
3. Same Indication Statement?	X		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?	X		If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?	X		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.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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 for home use 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:

6. Explain how new characteristics could or could not affect safety or effectiveness:

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

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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?		
4. If, not, has POS been notified?		
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)?		
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.		

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Screening Checklist
For all Premarket Notification 510(k) Submissions

Device Name:	K
Submitter (Company):	

Items which should be included (circle missing & needed information)	SPECIAL YES	SPECIAL NO	ABBREVIATED YES	ABBREVIATED NO	TRADITIONAL YES	TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
1. Cover Letter clearly identifies Submission as: a) "Special 510(k): Device Modification" b) "Abbreviated 510(k)" c) Traditional 510(k)	GO TO # 2,4		GO TO # 3,4,5		GO TO # 4,5	✓	
2. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE							
a) Name & 510(k) number of legally marketed (unmodified) predicate device							
b) *STATEMENT - INTENDED USE AND INDICATIONS FOR USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED**			* If no - STOP not a special				
c) *STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED**			* If no - STOP not a special				
d) Design Control Activities Summary							
i) 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							
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied							
iii) A declaration of conformity with design controls. The declaration of conformity should include:							
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met							
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.							9

DCRD form 102 (rev. 04/13/98 4:19 PM)

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

→ → → CONTINUE TO SECTION 4 ← ← ←

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
3. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS							
a) 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							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below							
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed							
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device							
v) A specification of any deviations from each applicable standard that were applied							
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference							
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations							
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards							

→ → → CONTINUE TO SECTION 4 ← ← ←

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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4. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
a) trade name, classification name, establishment registration number, address of manufacturer. device class					✓		
b) OR a statement that the device is not yet classified	FDA - may be a classification request; see coordinator						
c) identification of legally marketed equivalent device	NA				✓		
d) compliance with Section 514 - performance standards	NA						
e) address of manufacturer					✓		
f) Truthful and Accurate Statement					✓		
g) Indications for Use enclosure					✓		
h) SMDA Summary or Statement *(FOR ALL DEVICE CLASSES)*							
i) Class III Certification & Summary *(FOR ALL CLASS III DEVICES)*							
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals							
k) Proposed Labeling:					✓		
i) package labeling (user info)							
ii) statement of intended use							
iii) advertisements or promotional materials							
i) MRI compatibility (if claimed)							
m) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:							
i) labeling							
ii) intended use							
iii) physical characteristics							
iv) anatomical sites of use							
v) performance (bench, animal, clinical) testing							
vi) safety characteristics	NA						
n) If kit, kit certification	NA						
5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:					✓		
i) component & material							
ii) identify patient-contacting materials							
iii) biocompatibility of final sterilized product							
b) Sterilization and expiration dating information:					✓		
i) sterilization method							
ii) SAL							
iii) packaging							
iv) specify pyrogen free							
v) ETO residues							
vi) radiation dose							
c) Software validation & verification:							
i) hazard analysis							
ii) level of concern							
iii) development documentation							
iv) certification							

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening _____Yes_____No
Date:_____

Reviewer: [signature]
Concurrence by Review Branch:_____

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Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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MEMO TO THE RECORD
510(K) REVIEW
K982941

DATE: 11/12/98
OFFICE: HFZ-410
DIVISION: DGRD/PRSB
FROM: Biologist
DEVICE NAME: Hem-o-lok model numbers 523900, 523970
COMPANY NAME: Weck Closure Systems

Review: Weck has identified the following proposed changes to their Hem-O-Lok ligating clips:

1. A change to the description of the device as it relates to clip size. The current designations are Hem-O-Lok™ 3.0 and Hem-O-Lok™ 5.5. Weck intends to refer to these clips as medium and MLX, respectively.

2. A change in the indications for use which would replace any references to specific mm vessel sizes with a statement that surgeons should select clip size based on their experience, judgment, and needs.

I consulted with Dr. Dan Schultz regarding the change in indications for use. Dr. Schultz stated that the sponsor should provide some specific information regarding the device. He believed that the experience, judgment, and needs, phrase was not sufficient information. Dr. Schultz stated that the sponsor should include a statement indicating that the surgeon should use a clip large enough to occlude the subject vessel, i.e., that 3.0 clips should not be used to ligate vessels larger in diameter than 3.0 mm. He also asked if the sponsor had provided data proving that the clips could successfully ligate vessels of the sizes indicated. Dr. Schultz had no issue with the sponsor changing the name of the clips.

3. Weck has changed their supplier for the polyacetal material used in the clips. The original supplier was (B)(4) whereas the new supplier is (B)(4)

4. Weck has discontinued [redacted] (B)(4) to contract sterilize their devices.

INTENDED USE

Previous indications for use statement: Hem-O-Lok™ 3.0 ligating clips are intended for use on vessels between 1.0 and 3.0 mm in diameter. Hem-O-Lok™ ligating clips are designed for use specifically with Hem-O-Lok polymer ligating clips appliers. Other appliers can not be used (K941972).

The sponsor has another predicate device, Horizon Ligating Clips (K982313), have the following indications for use: Horizon Ligating Clips are indicated for procedures involving vessels or anatomic structures where ligating clips are the best choice. Select clip size, type and material

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Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

based upon experience, judgment and needs.

Proposed indications for use statement: Indicated for use in procedures involving ligation of vessels or small tissue structures. Surgeons should select clip size based on experience, judgment and needs.

Finalized indications for use statement: 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. These indications for use are identical to predicate indications for use and contain Dr. Schultz's recommended phrase regarding the size of the clip being appropriate for the size of the vessel being occluded.

DEVICE DESCRIPTION

a) Is the device:

1. Life-supporting or life-sustaining?	No.
2. Implant (short-term or long-term)?	Yes, long term.
3. Software-driven?	No.
4. Sterile?	Yes.
5. Single use?	Yes.
6. For home or prescription use?	Prescription.
7. Contain a drug or biologic component?	No.
8. A kit?	No.

b) Device(s) to which equivalence is claimed and its manufacturer(s):
(1) K941972: Hem-O-Lok clips (K922186, K902108), Weck
(2) K982313: Horizon Ligating Clips, Weck

SUMMARY

The Hem-O-Lok™ ligation clip is a manually applied hemostatic clip. The clip is nonabsorbable and is manufactured from polyacetal, Tenac® 5010. The clips are housed in a cartridge. The sponsor provided engineering drawings of the clip and the associated clip applier.

a) **MATERIALS:**

Polyacetal supplier changed (B)(4) [redacted] New material is called Tenac® 5010. Biocompatibility testing of the proposed device passed the following tests:

1. Cytotoxicity
2. Primary Skin Irritation
3. Buehler Patch Test (Sensitization)
4. Systemic toxicity
5. Genotoxicity: Ames mutagenicity test, Chromosomal aberration assay in CHO cells, CHO/HGPRT forward mutation assay
6. Implantation at 12, 26 and 52 weeks with Histopathology
7. Hemocompatibility

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

The test data included in Attachments 10-13 of the 1990 Hem-O-Lok® 510(k) (K902108) was established using the 3.0 "medium" clip. The tests evaluated the mechanical characteristics of the device, such as closing strength and leakage of occluded vessels. This information addresses Dr. Schultz's concern over test evaluation of the clips.

b) **STERILITY:**

(B)(4)

[redacted]

c) **PACKAGING:** The clips are housed in a cartridge and packaged in a rigid plastic blister with Tyvek coated lidding.

LABELING: Weck originally provided a package insert with the Hem-O-Lok™ clips. In this submission they have removed the package insert from the product and have included information from the package insert that they feel is necessary for the safe and effective use of the clips on the sales unit label. The changes do not remove information critical to the safe use of the device. The sponsor has provided a new 510(k) summary and has stated that the new label will incorporate the change in the indications for use. The sponsor also has elected to remove the expiration date from their label until they have sufficient data to support it.

e) **SAFETY AND EFFECTIVENESS INFORMATION:** The sponsor has provided a summary of safety and effectiveness information.

f) **RECOMMENDATION:** Substantially equivalent to Implantable clip, FZP

g) **CLASSIFICATION:** Class II

P L Hudson 11/12/98

Peter L. Hudson, Ph.D.
Reviewer
Division of General and Restorative Devices
Plastic and Reconstructive Surgery Branch

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

WECK CLOSURE SYSTEMS

November 11, 1998

Mr. Peter Hudson
Office of Device Evaluation, DCRND
C/O Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Re: Additional expiration information for Hem-O-Lok® 510(k) submission K982941.

Dear Mr. Hudson,

This letter is in response to our telephone conversation earlier today. As discussed, we have decided to initially market the Hem-O-Lok® clips described in K982941 without an expiration date. Weck Closure Systems reserves the right to add an expiration date at some later point in time once we have had an opportunity to collect supportive real time data.

Sincerely,

Brian J. Young
Regulatory Affairs Manager

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Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

One Weck Drive, P.O. Box 12600, Research Triangle Park, NC 27709

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

WECK CLOSURE SYSTEMS

November 9, 1998

Mr. Peter Hudson
Office of Device Evaluation, DCRND
C/O Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Re: Additional information requested for Hem-O-Lok® 510(k) submission K982941.

Dear Mr. Hudson,

This letter is in response to your request for additional information.

The agreed upon indications for use listed below will be used on the product label in place of the "Indications" statement listed in Table 1 of the initial K982941 submission. The attached Premarket Notification [510(k)] Summary has been updated accordingly.

> *"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."*

Expiration dating of the Hem-O-Lok® clips described in K982941 will be based upon an accelerated aging model using Arrhenius theory[1]. Our approach includes a challenge of the product material and the sterile product packaging[2]. Thus far we have data which would support a one year expiration date (we have established five years expiration for the packaging and at least one year of expiration for the clip material). Weck Closure Systems reserves the right to extend Hem-O-Lok® expiration dating provided that sufficient data can be established to support the extension.

I hope that this information adequately addresses your request. Please call me if you require any additional information. I can be reached at 919/361-4041.

---

[1] e.g., "Accelerated Aging of Packaging: Considerations, Suggestions, and Use in Expiration Date Verification", Reich, R. Robert, Medical Device and Diagnostic Industry, vol. 10, no. 3, March, 1988, p. 34-36, 38-39.

[2] Product performance of aged product is challenged by subjecting the clips to stress conditions and ensuring adequate clip closure without any failures. Package integrity acceptance is based on USP 23.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

One Weck Drive, P.O. Box 12600, Research Triangle Park, NC 27709

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Sincerely,

Brian J. Young
Regulatory Affairs Manager

Attached:
Premarket Submission [510(k)] Summary

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

K982941/A2

WECK CLOSURE SYSTEMS

November 9, 1998

Mr. Peter Hudson
Office of Device Evaluation, DCRND
C/O Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

RECEIVED
10 NOV 98 12 03
FDA/CDRH/OCE/DMC

Re: Additional sterilization information requested for Hem-O-Lok® 510(k) submission K982941.

Dear Mr. Hudson,

This letter is in response to your request for additional information regarding Ethylene Oxide sterilization of Hem-O-Lok® ligating clips.

Weck Closure Systems is using elements of ANSI/AAMI/ISO 11135 "Guideline for Industrial Ethylene Oxide Sterilization of Medical Devices" (1994) and AAMI TIR No. 16 – 1998, Process Development and Performance Qualification for Ethylene Oxide Sterilization – Microbiological Aspects, as a basis for sterilization validation of Hem-O-Lok®.

Residual sterilant testing and limits are based upon ANSI/AAMI/ISO 10993-7:1995. The Hem-O-Lok® device is in the permanent contact device category of patient contact. Based on the permanent contact categorization, [redacted] (B)(4) Specifica[redacted]

I hope that this information adequately addresses your request. Please call me if you require any additional information. I can be reached at 919/361-4041.

Sincerely,

Brian J. Young
Regulatory Affairs Manager

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

One Weck Drive, P.O. Box 12600, Research Triangle Park, NC 27709

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

K982941/A1

WECK CLOSURE SYSTEMS

FDA/CDRH/ODE/DMC
6 Nov 03 11 03
RECEIVED

November 5, 1998

Mr. Peter Hudson
Office of Device Evaluation, DCRND
C/O Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Re: Additional information requested for Hem-O-Lok® 510(k) submissions 982941.

Dear Mr. Hudson,

This letter is in response to your request for additional information regarding the 510(k) submission indicated above.

We have changed the indications for use to include the statement that surgeons should match the size of the clip with the size of the vessel to be ligated (see attached Statement of indications for use).

The test data included in Attachments 10 – 13 of the 1990 Hem-O-Lok® 510(k) (K902108) was established using the 3.0 "Medium" clip.

Also, the name of the 5.5 "Large" clip is being changed to MLX.

I hope that this information adequately addresses your request. Please call me if you require any additional information. I can be reached at 919/361-4041.

Sincerely,

Brian J. Young
Regulatory Affairs Manager

Attachment:
Revised Statement of indications for use for K982941

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SK-13

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
One Weck Drive, P.O. Box 12600, Research Triangle Park, NC 27709

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

WECK CLOSURE SYSTEMS

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 (B)(4) Specifications [redacted] The blister packs are fitted into an overpack carton which serves as the sales unit.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

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.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

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

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Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

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

August 21, 1998

WECK CLOSURE SYSTEMS
1 WECK DR.
RESEARCH TRIANGLE PARK, NC 27709
ATTN: JAMES L. LUCKY

510(k) Number: K982941
Received: 21-AUG-1998
Product: HEM-O-LOK MODEL NUMBERS 523900, 523970

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.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. 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 Assistance (DSMA) 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 (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. 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 DSMA 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

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Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

K982941

WECK CLOSURE SYSTEMS

August 17, 1998

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

FDA/CDRH/CDE/DMC
21 Aug 98 2:11
RECEIVED

Re: 510(k) Notification for modification to Hem-O-Lok™ Ligating Clips

Dear Sir or Madam,

This 510(k) submission is for a modification to the labeling of Hem-O-Lok™ ligating clips (ref. K941972).

Weck[1] originally provided a package insert with the Hem-O-Lok™ clips. We are proposing to remove the package insert from the Hem-O-Lok™ clips, and to include all information from the package insert necessary for the safe and effective use of the clips on the sales unit label.

We are also proposing the following additional labeling changes:

- A change to the description of the device as it relates to clip size. The current designations are Hem-O-Lok™ 3.0 and Hem-O-Lok™ 5.5. The current clip name is not consistent with the naming convention used by Weck on other similar products. A more useful designation, and one consistent with Weck's approach to naming other similar products is to use descriptive language to name the clips by comparative size, e.g., "Medium" for the 3.0 mm, and "Large" for the 5.5 mm. An illustration of the clip will be included in the labeling to communicate actual clip size.
- A change in the indications for use which would replace any references to specific mm vessel sizes with a statement that surgeons should select clip size based on their experience, judgement, and needs. The current indications provide that the 3.0 mm clips are intended for use on vessels from 1.0 to 3.0 mm in diameter and the 5.5 mm clips are intended for use on 3.0 – 5.5 mm vessels. Surgeons don't measure vessels with micrometers prior to ligation, but rather rely upon their judgement to apply appropriate size ligating clips. Therefore the revised indications are a more appropriate description of the relationship between vessel size and corresponding clip size.

Additional information in support of the labeling changes is included in the body of this 510(k) submission (see Section 1).

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CV Class SF 14-II

[1] Pilling Weck, Inc. is listed as the sponsor of K941972. Pilling Weck split into two separate entities in 1997, Pilling Weck Surgical (surgical instruments) and Weck Closure Systems (ligation and other products). Weck Closure Systems is still at the One Weck Drive, Research Triangle Park, NC address identified in K941972.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

One Weck Drive, P.O. Box 12600, Research Triangle Park, NC 27709

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

We also wish to inform FDA that we have changed suppliers for the polyacetal material used in the clips and have (B)(4) Specifications to contract sterilize the clips.

The original clip supplier was (B)(4) The trade name of the polyacetal material supplied by (B)(4) was Delrin® 500 whereas the tradename of material supplied by (B)(4) is Tenac® 5010. Biocompatability data for the Tenac is included in the body of the submission (see Section 9).

Weck no longer performs ethylene oxide sterilization of the Hem-O-Lok™ clips in-house. We have qualified (B)(4) to contract sterilize other similar products.

Please call me if you require any additional information. I can be reached at 919/361-4041.

Sincerely,

Brian J. Young
Regulatory Affairs Manager

Attachments:
1. Premarket Submission Cover Sheet
2. Body of Submission

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Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Premarket Submission Cover Sheet

Date of Submission: August 17, 1998 ~~July 24, 1998~~ 8/17/98

FDA Document Number:

Section A — Type of Submission

- ☒ 510(k)
- ☐ 510(k) Add'l information
- ☐ IDE
- ☐ IDE Amendment
- ☐ IDE Supplement
- ☐ IDE Report
- ☐ PMA
- ☐ PMA Amendment
- ☐ PMA Report
- ☐ PMA Supplement - Regular
- ☐ PMA Supplement - Special
- ☐ PMA Supplement - 30 day
- ☐ PMA Supplement - Panel Track

Section B1 — Reason for Submission — 510(k)s Only

- ☐ New device
- ☐ Additional or expanded indications
- ☐ Change in technology, design, materials, or manufacturing process
- ☒ Other reason (specify): Labeling Changes

Section B2 — Reason for Submission — PMAs Only

- ☐ New device
- ☐ Withdrawal
- ☐ Additional or expanded indications
- ☐ Licensing agreement
- ☐ Change in design, component, or specification:
  - ☐ Software
  - ☐ Color Additive
  - ☐ Other (specify below)
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf life
  - ☐ Trade name
  - ☐ Other (specify below)
- ☐ Process change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Report submission:
  - ☐ Annual or periodic
  - ☐ Post-approval study
  - ☐ Adverse reaction
  - ☐ Device defect
  - ☐ Amendment
- ☐ Response to FDA correspondence (specify below)
- ☐ 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 B3 — Reason for Submission — IDEs Only

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion / extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Change in:
  - ☐ Correspondent
  - ☐ Design
  - ☐ Informed consent
  - ☐ Manufacturer
  - ☐ Manufacturing
  - ☐ Protocol – feasibility
  - ☐ Protocol– other
  - ☐ Sponsor
- ☐ Response to FDA letter concerning:
  - ☐ Conditional approval
  - ☐ Deemed approved
  - ☐ Deficient final report
  - ☐ Deficient progress report
  - ☐ Deficient investigator report
  - ☐ Disapproval
  - ☐ Request extension of time to respond to FDA
  - ☐ Request meeting
- ☐ Emergency use:
  - ☐ Notification of emergency use
  - ☐ Additional information
- ☐ Report submission:
  - ☐ Current investigator
  - ☐ Annual progress
  - ☐ Site waiver limit reached
  - ☐ Final
- ☐ IOL submissions only:
  - ☐ Change in IOL style
  - ☐ Request for protocol waiver
- ☐ Other reason (specify):

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Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

FDA Document Number:

Section C — Product Classification

Product code: FZP	C.F.R. Section: 21 CFR 878.4300	Device class: ☐ Class I ☒ Class II ☐ Class III ☐ Unclassified
Classification panel: Cardiovascular		

Section D — Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

1 523900	2 523970	3	4
5	6	7	8

Summary of, or statement concerning, safety and effectiveness data:
☒ 510(k) summary attached
☐ 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K941972	1 Hem-O-Lok™	1 Pilling Weck, Inc.
2	2	2
3	3	3
4	4	4
5	5	5
6	8	8

Section E — 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™	1 523900
2 Hem-O-Lok™	2 523970
3	3
4	4
5	5
6	6

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

1	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: ☐ Laboratory testing ☐ Animal trials ☐ Human trials

Indications (from labeling):
Hem-O-Lok polymer ligating clips are intended for use in procedures involving vessels or small tissue structures. Surgeons should select clip size based on their experience, judgement, and needs.

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Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

FDA Document Number:

Section F — Manufacturing / Packaging / Sterilization Sites

☒ Original ☐ Add ☐ Delete	FDA establishment registration number: 1044475	☒ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name: Weck Closure Systems			
Division name (if applicable): N/A		Phone number (include area code): (919) 361-4043	
Street address: One Weck Drive		FAX number (include area code): (919) 361-3914	
City: Research Triangle Park	State / Province: NC	Country: USA	ZIP / Postal Code: 27709
Contact name: James L. Lucky			
Contact title: Director, Regulatory Affairs and Quality Assurance			
☐ Original ☒ Add ☐ Delete	FDA establishment registration number: 1018470	☐ Manufacturer ☐ Contract manufacturer	☒ Contract sterilizer ☐ Repackager / relabeler

(B)(4) Specifications

[redacted]

☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name:			
Division name (if applicable):		Phone number (include area code): ( )	
Street address:		FAX number (include area code): ( )	
City:	State / Province:	Country:	ZIP / Postal Code:
Contact name:			
Contact title:			

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Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

	FDA Document Number:

Section G Applicant or Sponsor

Company / Institution name: Weck Closure Systems	FDA establishment registration number: 1044475
Division name (if applicable): N/A	Phone number (include area code): (919) 361-4041
Street address: One Weck Drive	FAX number (include area code): (919) 361-3914

City:	State / Province:	Country:	ZIP / Postal Code:
Research Triangle Park	NC	USA	27709

Signature: Brian J Young

Name: Brian J. Young

Title: Regulatory Affairs Manager

Section H Submission correspondent (if different from above)

Company / Institution name:	
Division name (if applicable):	Phone number (include area code): ( )
Street address:	FAX number (include area code): ( )

City:	State / Province:	Country:	ZIP / Postal Code:

Contact name:

Contact title:

Your voluntary completion of this Premarket Submission Cover Sheet will not affect any FDA decision concerning your submission, but will help FDA's Center for Devices and Radiological Health process your submission more efficiently. The information you provide should apply *only* to a single accompanying submission. Please do not send cover sheets for any previous submissions. See the instructions for additional information on completing the cover sheet. If you have a question concerning completion of the cover sheet, please contact the Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

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Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(purposefully left blank)	10
(purposefully left blank)	11
(purposefully left blank)	12

30

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

AVERY™ Table 'n Tabs™ Dividers

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PAGINATION

SECTION	PAGES INCLUDED
1	1-1 through 1-6 1A (1A1 - 1A5) 1B (1B1 - 1B3) 1C (1C1 – 1C-2)
2	2-1 only
3	3-1 and two attachments
4	4-1 only
5	5-1 only
6	6-1 and 2 page 510(k) summary
7	7-1 only
8	8-1 only
9	9-1 Attachment A from G95-1 Cytotoxicity - 1 only Sensitization - 1 only Irritation -1 only Acute Systemic Toxicity - 1 only Rabbit Pyrogen - 1only Ames - 1 through -5 Chromosomal Aberration - 1 through -14 CHO/HGPRT - 1 through -19 52 Week Implant - 1 through 20

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

1 Labeling Change Summary

SUMMARY OF THE PROPOSED LABELING CHANGE
SAMPLE LABELS AND LABELING
DISCUSSION SUPPORTING THE LABELING CHANGE
CONCLUSIONS

SUMMARY OF THE LABELING CHANGE

Weck originally provided a package insert with the Hem-O-Lok™ clips. We are proposing to remove the package insert from the Hem-O-Lok™ clips, and to include information from the package insert necessary for the safe and effective use of the clips on the sales unit label.

Table 1 provides a comparison of the information included in the original package insert and that included in the proposed sales unit label. The 3.0 (medium) clip labeling is the representative labeling used.

We are proposing a modification to the description of the device as it relates to clip size. The current designations are Hem-O-Lok™ 3.0 and Hem-O-Lok™ 5.5 clips. We believe that these designations may be confusing to surgeons because the existing label does not clearly identify what the numbers refer to. A more useful designation is to name the clips based on comparative size, e.g., "Medium" for the 3.0 mm and "Large" for the 5.5 mm clips. Weck uses the proposed nomenclature for other similar products, e.g., Hemoclip Titanium clips (see samples included in Attachment 1C).

We are also proposing a modification to the indications for use statement. The current indications identify specific vessel sizes, e.g., 3.0 to 5.5 mm. Surgeons don't actually measure vessels prior to applying ligating clips but rather rely upon their judgement and experience to match clip size to vessel size. With this in mind we have replaced any references to specific mm vessel sizes with a statement that surgeons should rely on their experience, judgement and needs in selecting an appropriate sized clip for any particular vessel. The revised indication is consistent with that used by Weck on other similar ligating clips, e.g., Horizon Clips (see Attachment C).

SAMPLE LABELS AND LABELING

Attachment 1A - Original labels and labeling included in K941972.

Attachment 1B - Representative sample of proposed sales unit label.

Attachment 1C - Samples of similar Hemoclip labels. The indications for use statement included in K982313 for similar Horizon ligating clips.

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DISCUSSION SUPPORTING THE PROPOSED CHANGE

1. Discussion regarding the removal of the package insert

Surgeons and surgical assistants are intimately familiar with the use of clips and appliers. The information users need to safely and effectively use ligation clips is as follows:

- Clips are supplied sterile and should not be resterilized.

  Important because clips are supplied in cartridges containing several clips. A particular surgical procedure may only require the use of a few of the total number of clips supplied in a sterile unit cartridge. Hospitals are taking steps to reduce costs associated with providing patient care and could view resterilization of unused clips as a viable approach absent the sterile, single use statement.

- Clip and applier compatibility information.

  Important because there are a variety of different clips and appliers on the market. Subtle and not so subtle differences between manufacturers and products lines require that clip and applier types be matched in order for them to be used safely and effectively.

- Color coding of clips and appliers.

  Important because the clip size and applier jaw size must be matched for proper vessel/tissue closure. Hem-O-Lok™ clip cartridges and corresponding applier handles are color coded by clip size. Color coding is now used by virtually all clip/applier manufacturers.

- Clip material type.

  A variety of different clip materials are available for use in ligation, e.g., titanium, tantalum, stainless steel, and polymers. Differences in the properties of the various material types are important for surgical selection and use.

- Indications for use.

  Important to assure that the device is used according to the design intent and claims of the manufacturer.

- Contraindications.

  Important to assure that users are aware of procedures and uses of the device where the risk of use outweighs any foreseeable benefits.

All of the above listed information necessary for the safe and effective use of the clips is provided on the modified clip labels. A separate insert is not required for the safe and effective use of the clips.

- ➢ Table 1 provides a point by point comparison of the original package insert and the proposed clip sales unit. Where differences exist the company's rationale for the change is provided.

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2. Discussion regarding the change in size description and indications for use

Weck typically identifies clip size using descriptive language, e.g., small, medium, large, etc. The Hem-O-Lok™ 3.0 and 5.5 designations were an exception to this naming convention. Surgeons don't measure vessels prior to ligation and therefore identification by mm clip size is confusing and not in keeping with existing size characterizations by Weck. The proposed change brings the size descriptives and indications used on Hem-O-Lok™ in line with that used by Weck on other similar products (see Attachment 1C).

CONCLUSIONS

The proposed change is a well thought improvement to Hem-O-Lok™ labeling based on our experience with other similar products. All information necessary for the safe and effective use of the clips has been transferred from the package insert to the clip sales unit label. Information from the clip package insert which pertains to the appliers is now included in the applier package insert.

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Table 1

Comparison of information included on original package insert and that included on the proposed sales unit label.

Original Package Insert Included in K941972	Proposed Sales Unit Label
Weck Hem-O-Lok™ 3.0 Nonabsorbable polymer ligating clips. **Description:** Hem-O-Lok™ ligating clips are produced from a nonabsorbable polymer (polyacetal). The Hem-o-Lok™ ligating clip is designed for the ligation of blood vessels and other small tissues structures. The Hem-O-Lok™ ligating clips is positioned around a vessel and closed by applying pressure to the ring handles of the Hem-O-Lok™ ligating clip applier until the clip locks shut. **Indications:** Hem-O-Lok™ 3.0 ligating clips are intended for use on vessels between 1.0 and 3.0 mm in diameter. Hem-O-Lok™ ligating clips are designed for use specifically with Hem-O-Lok™ polymer ligating clips appliers. Other appliers can not be used. **Contraindications:** This product is not intended for use as a contraceptive tubal occlusion device, but may be used to achieve hemostasis following transection of the fallopian tube. Do not use Hem-O-Lok™ polymer ligating clips on the following vessels: iliac, hepatic, renal carotid, or pulmonary arteries. Use on appropriate size vessels only. Do not use if the Hem-O-Lok™ has been resterilized. Do not use Hem-O-Lok™ appliers that are not functioning properly.	**Weck Hem-O-Lok™ Medium** Nonabsorbable polymer ligating clips. **Description:** [This section heading will not be included. The clip material is included in the device description (Hem-O-Lok™ Nonabsorbable polymer ligating clips). The remaining information from this section is either included in the indications for use section or rightly included in the corresponding applier package insert.] **Indications:** Indicated for use in procedures involving ligation of vessels or small tissue structures. Surgeons should select clip size based on experience, judgement and needs. **Contraindications:** Not intended for use as a contraceptive tubal occlusion device. Do not use on the iliac, hepatic, renal carotid, or pulmonary arteries. [The last two sentences were excluded as they are not true contrainidications. Appropriate vessel size is at the discretion of the physician as indicated in the revised indications for use. The statement regarding the applier rightly belongs in the applier package insert.]

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Original Package Insert Included in K941972	Proposed Sales Unit Label
Warnings: Hem-O-Lok ligating clip appliers should be checked for functionality prior to use. Appliers in need of repair should be returned to Linvatec (Weck Endoscopy) for repair or replacement. Call Linvatec Customer Service for instructions. The use of Hem-O-Lok™ ligating clip appliers which are not functioning properly may result in inadequate function of the clip. Do not resterilize Hem-O-Lok™ ligating clips or Hem-o-Lok ligating clip cartridges.	**Warnings:** [This section heading is not included in the proposed clip sales unit label. The sterilization instructions for the clip are "Single Use. Sterilized by EtO. Do not resterilize." The remaining instructions are rightly included in the applier labeling.]
Precautions: Always disssect the vessel from surrounding tissue prior to ligation. Care should be taken to ensure that the tissue to be occluded fits within the legs of the clip. Leave adequate margins between the ligation point and the site to be transected. Inadequate margin may cause the clip to slip off the vessel. Some surgeons prefer double clipping each ligation to ensure safety. The surgeon should inspect the ligation site after application of each Hem-O-Lok™ ligating clip for leakage and to ensure proper closure. This is a disposable product. Resterilization may cause product dysfunction.	**Precautions:** The clip must be latched to ensure proper ligation of the vessel or tissue. Inspect the ligation site after application to ensure proper closure. This product is not designed for use as a tissue marker. [The proposed labeling is a more direct succinct statement of precautions. Application of double clips is at the discretion of the physician. It is not a safety issue. The product is already labeled as a single use device therefore additional resterilization language is unnecessary.]
How Supplied: Hem-O-Lok™ ligating clips are supplied sterile, ready to use. Hem-O-Lok™ ligating clip appliers are available separately, and are furnished non-sterile. They must be sterilized before use.	**How Supplied:** [This section heading not included. The sterilization instructions and the statement For use only with Hem-O-Lok™ appliers is included elsewhere on the new label.]
Directions for use: 1. The Hem-O-Lok 3.0 ligating clip is intended to be used where, based upon the experience of the surgeon and consistent with the size of the tissue being ligated, the 3.0 clip would be indicated. 2. Grasping one side of the applier, carefully insert jaws of the applier into the cartidge slot making sure the jaws are perpendicular to the surface of the cartridge. Applier should be gently inserted over the clip until it stops. Do not force the applier into the cartridge or onto the clip. The applier should enter and withdraw from the cartridge easily. 3. Remove the applier from the cartridge with the clip securely in the applier jaw. If the cartridge is not held by the Hem-O-Lok cartridge base, it may be necessary to hold the cartridge to allow the clip to be removed.	**Directions for use:** [This section heading is not included in the proposed label. Statement #1 is a reiteration of information already included in the indications for use. The remaining statements are rightly included in the applier labeling.]

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Original Package Insert Included in K941972	Proposed Sales Unit Label
4. The loaded applier is now ready for the surgeon to apply the Hem-O-Lok™ clip. 5. The clip is positioned around the tissue that is to be ligated. The surgeon should apply sufficient force to the applier ring handles to close the applier until the clip locks shut. The applier is removed by releasing the pressure on the applier ring handles until the applier returns to the fully open position, at which time the applier can be smoothly withdrawn from the ligation site.	
<u>Other information included on the label</u>	<u>Other information included on the label</u> Illustration of Hem-O-Lok™ clip.
	Use only with Hem-O-Lok™ medium appliers. Sterile, Single Use Disposable. Do not resterilize. Eto Sterilized. Lot XXXXXX Exp XXXXXX Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Made in the USA.
U.S. patents 4834096, 5062846, 5100416. Additional patents pending.	U.S. patents 4834096, 5062846, and 5100416.
Edward Weck Inc. Research Triangle Park, NC 27709	Weck Closure Systems One Weck Drive Research Triangle Park, NC 27709

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ATTACHMENT 1A

Original Labels and labeling included with K941972.

	Pg.
• **Individual sterile pouch lid**	**1A-1**
• **Package Insert**	**1A-2**
• **Promotional literature**	**1A-3**

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EXCEPT AS NOTED
ALL COPY PRINTS BLACK

THIS COPY PRINTS PMS 302

PEEL

Sterile, Single Use, Disposable
Do Not Resterilize.
Sterility is not guaranteed if package has been opened or damaged.
Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

WECK
Hem-o-lok® Polymer MED

Hem-o-lok Polymer Ligating Clips
Cat. No. 523900
10 Medium Clips

Weck Week Inc., Research Triangle Park, N.C. 27709 Made in U.S.A. 1

PEEL

LANE DESIGNATION NUMBERS
(1,2,3,4,5,6,7,8,9,10,11,12)

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1A-1

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(B)(4) Draft

[redacted]

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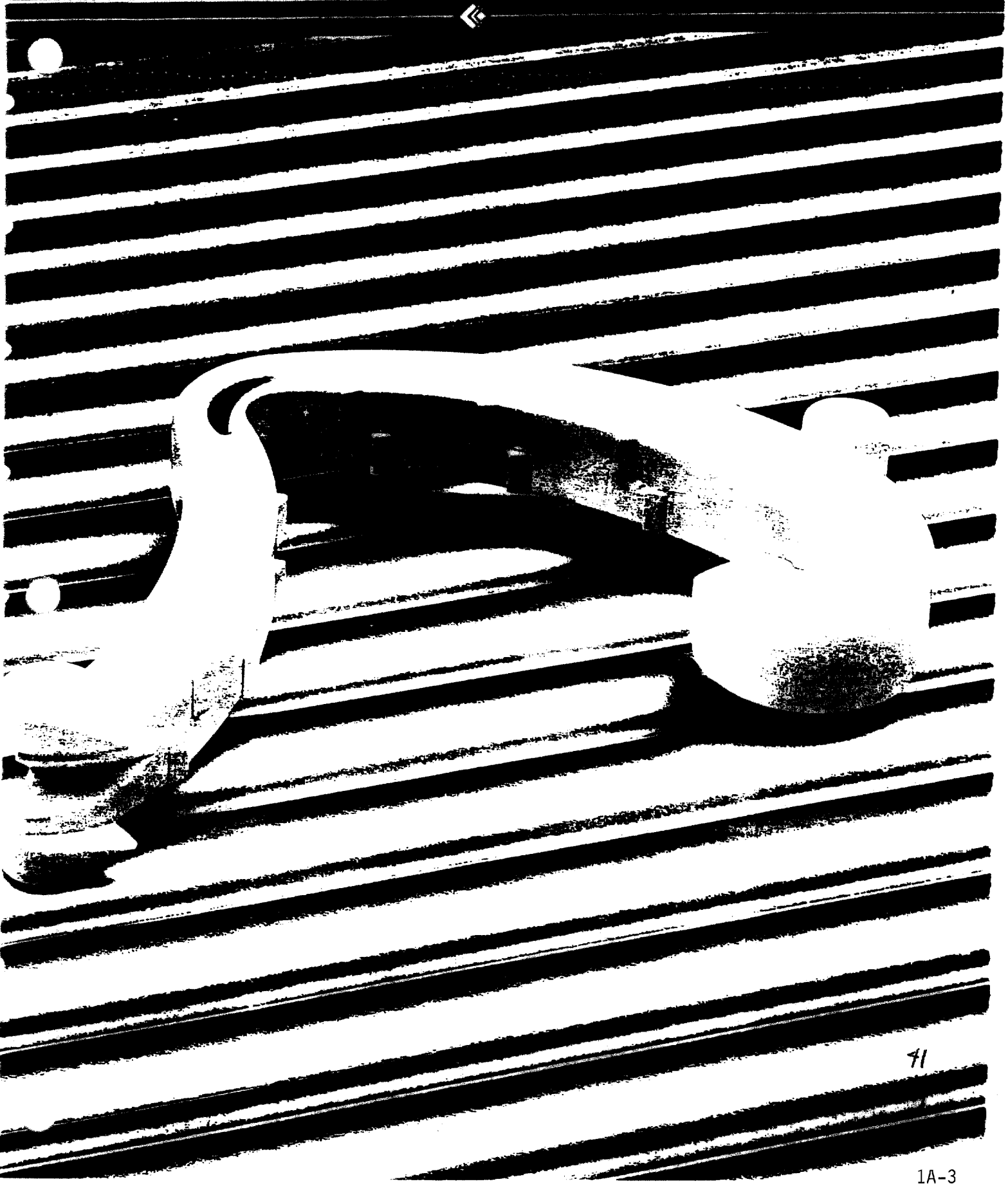
1A-2

(B)(4) Draft

[redacted]

796-8118

WECK® HEM-O-LOK® Ligating Clip.



41

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Linvatec
Weck Endoscopy

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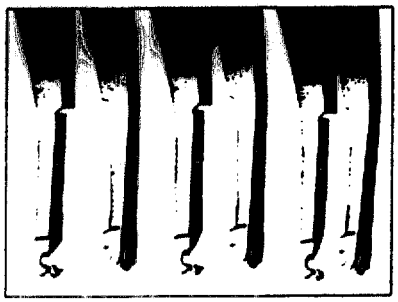
Clinically Proven Polymer Material

The HEM-O-LOK ligating clip is made of polyacetal p[illegible]ner, a material which has been safely used for more than twenty years in artificial joints. The unique properties of this polymer include radiolucency which eliminates MRI, CT scan and x-ray distortion associated with metal ligating clips. Since the HEM-O-LOK clip is nonabsorbable, it eliminates the unpredictable absorption rates common with absorbable clips.

One-hand loading is easy with the HEM-O-LOK system. A soft audible "click" signals the clip is loaded securely into the applier.

Visual Elimination Of Dropped Clips

The HEM-O-LOK applier design allows the ligating clip to *lock* in the applier. Clips won't push back in the applier or fall out during loading, passing or ligating. The HEM-O-LOK clip can be flexed without falling out of the applier. This is particularly helpful when entering an endoscopic cannula.



Instrument transfer is much easier. Even squeezing the applier during a pass will not cause the clip to fall out.

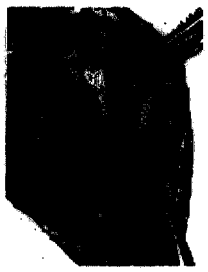
Minimal Tissue Dissection

The patented* HEM-O-LOK penetrating latch closes through surrounding tissue, minimizing vessel dissection. Ligation is faster and easier than conventional methods.

Tedious dissection is minimized as the HEM-O-LOK latch closes through surrounding tissue.

Unsurpassed Ligation Security

The HEM-O-LOK ligating clip completely encompasses a vessel, much like a ligature. Once closed, it is virtually impossible to inadvertently remove or dislodge. The HEM-O-LOK clip offers at least twice the occlusion force of metal ligating clips. In addition, the patented* design actually increases the occlusion force as more vessel mass is ligated. As a result, a wider range of vessel sizes may be ligated with one clip.



Another soft "click", and a light tactile response through the applier signals the clip is secured tenaciously on the vessel.

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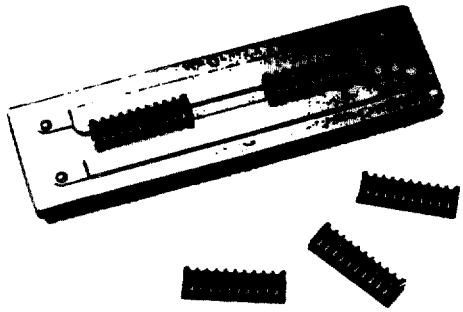
[redacted]

The 3.0 polymer clip is designed to be used on vessels from 1.0 to 3.0mm in diameter. The patented* design of the HEM-O-LOK cartridge and appliers provides smooth, easy loading. In addition, the HEM-O-LOK cartridge conveniently fits existing WECK HEMOCLIP® bases.



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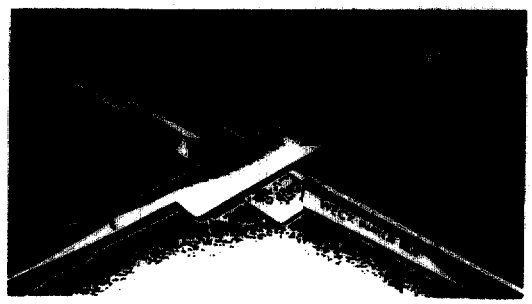
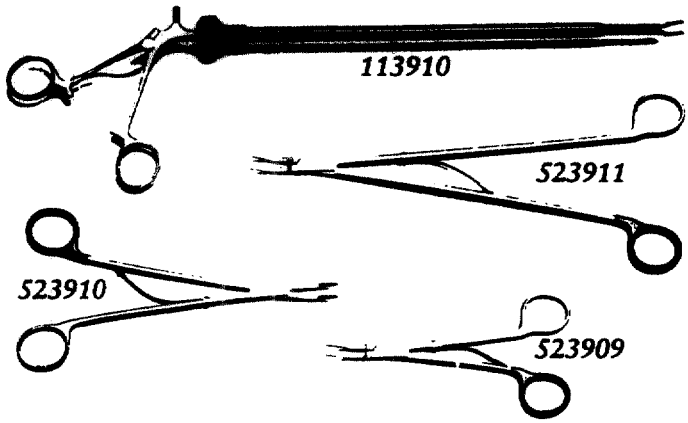


HEM-O-LOK Appliers are designed for easy cleaning. As a result, instrument processing protocol can be followed easily, insuring patient safety.



Ordering Information

Cat. No.	Description	Quantity
523900	HEM-O-LOK 3.0 Polymer clips 10 clips per cartridge	12 cartridges per box

Cat. No.	Description	Length
523909	HEM-O-LOK 3.0 Ligating Clip Applier	6"
523910	HEM-O-LOK 3.0 Ligating Clip Applier	8"
523911	HEM-O-LOK 3.0 Ligating Clip Applier	10.75"
113910	HEM-O-LOK 3.0 Endoscopic Applier	11.6" Shaft Length
523120	HEM-O-LOK Remover	6.5"
523121	HEM-O-LOK Remover	10.5"
113914	HEM-O-LOK Endoscopic Remover	11.6" Shaft Length
523130	HEM-O-LOK Base	

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*Covered by US patent numbers 4834096, 5062846, 5100416.
Additional patents pending.

Linvatec Weck Endoscopy

099407 9/92 20M

11311 Concept Blvd, Largo, Florida 34643 (800) 237-0169

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ATTACHMENT 1B

Representative sample of proposed clip label sales unit label and promotional materials

	Pg.
• **Proposed Sales unit box label**	**1B-1**
• **Proposed promotional material**	**1B-2**

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Hem-O-Lok™ Medium **(DRAFT)**
Nonabsorbable Polymer Ligating Clips

Indications:
Indicated for use in procedures involving ligation of vessels or small tissue structures. Surgeons should select clip size based on experience, judgement and needs.

Contraindications:
Not intended for use as a contraceptive tubal occlusion device. Do not use on the iliac, hepatic, renal carotid, or pulmonary arteries.

Precautions:
The clip must be latched to ensure proper ligation of the vessel or tissue. Inspect the ligation site after application to ensure proper closure. This device is not designed for use as a tissue marker.

Illustration of Hem-O-Lok™ clip.

Use only with Hem-O-Lok™ medium appliers.
Sterile, Single Use Disposable. Do not resterilize.
Eto Sterilized.
Lot XXXXXX
Exp XXXXXX

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Made in the USA.

U.S. patents 4834096, 5062846, and 5100416.

Weck Closure Systems
One Weck Drive
Research Triangle Park, NC 27709

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Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hem-o-Lok Clip and Cartridge.

The large polymer clip is designed to be used on vessels from 2.0mm and above, in diameter, according to the judgement of the surgeon. The patented* design of the Hem-O-Lok cartridge and appliers provide smooth, easy loading. In addition, the Hem-O-Lok cartridge conveniently fits existing Weck Hemoclip® bases. The Hem-O-Lok cartridge is also provided with adhesive strips for convenient placement on Mayo stand, gowns, patient-draping, gloves. Hem-O-Lok non-absorbable clips are an ideal clip companion to increasingly popular absorbable internal staples. Closure stop on endo applier facilitates pre-closure of clip down cannula. Internal teeth on clip help create unparalleled traction on vessel. Flexibility of material assures closure of tiny vessels and large vessels, by accommodating each size.

Easy Clean Appliers

Hem-o-Lok Appliers are designed for easy cleaning. As a result, instrument processing protocol can be followed easily, insuring patient safety.

(Product Information, e.g. catalog number, qty per pkg)

Strong jaw angle on endoscopic applier for visibility advantage.

Clinically Proven Polymer Material

The Hem-O-Lok ligating clip is made of polyacetal polymer, a material which has been safely used for more than twenty years in artificial joints. The unique properties of this polymer include MRI, CT scan and x-ray minimizes distortion associated with metal ligating clips. Since the Hem-O-Lok clip is categorized as a non-absorbable, it eliminates the unpredictable absorption rates common with absorbable clips as well as the possibility of toxic reaction to metal ion release that might be engendered by electrolytic reaction to surrounding implants as in orthopedic surgery.

Virtual Elimination of Dropped Clips

The Hem-O -Lok applier design allows the ligating clip bosses to fit into notches in the applier. Clips won't push back in the applier or fall out during loading, passing or ligating. The Hem-O-Lok clip can be flexed without falling out of the applier. This is particularly helpful when entering an endoscopic cannula. The clip may be pre-compressed for passage down a cannula. The non-absorbable composition of the Hem-O-Lok clip allows it to be trim, low-profile, compared to absorbable ligating clips.

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Minimal Tissue Dissection

The patented* Hem-O-Lok penetrating latch closes through surrounding tissue, minimizing vessel dissection. Ligation is faster and easier than conventional methods. Low profile, similar to metal clip profile.

Unsurpassed Ligation Security

The Hem-o-Lok ligating clip completely encompasses a vessel, much like a ligature. Once closed, it is virtually impossible to inadvertently remove or dislodge. The Hem-O-Lok clip offers at least twice the occlusion force of metal ligating clips. In addition, the patented* design actually increases the occlusion as more vessel mass is ligated. As a result, a wider range of vessel sizes may be ligated with one clip. It is 100% secure. The Hem-o-Lok clip lock provides tactile, visual.

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ATTACHMENT 1C

Representative sample of labeling for similar Hemoclip ligation clips (K841547, K841548, and K841549). Indications for use from similar Horizon Ligating clips (K982313).

	Pg.
• **Hemoclip Sterile unit labels**	**1C-1**
• **Indications for use for Horizon clips**	**1C-2**

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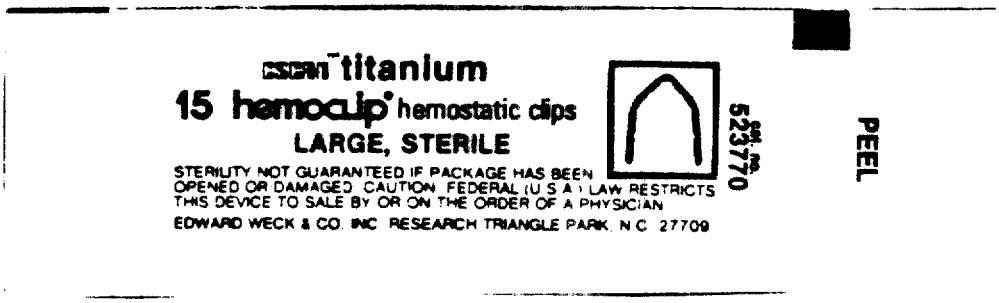
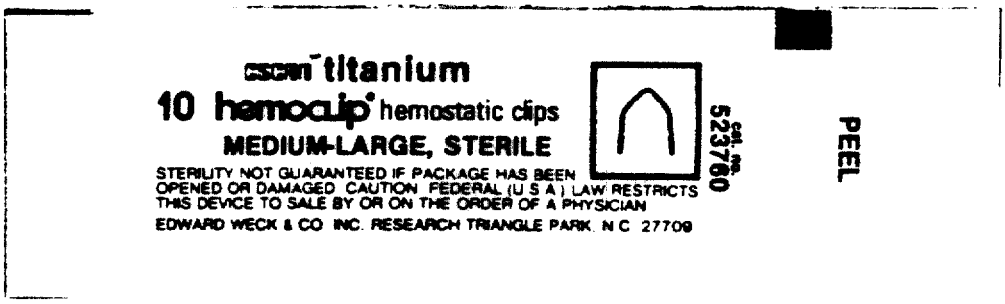
510(K) NOTIFICATION
PAGE FIVE

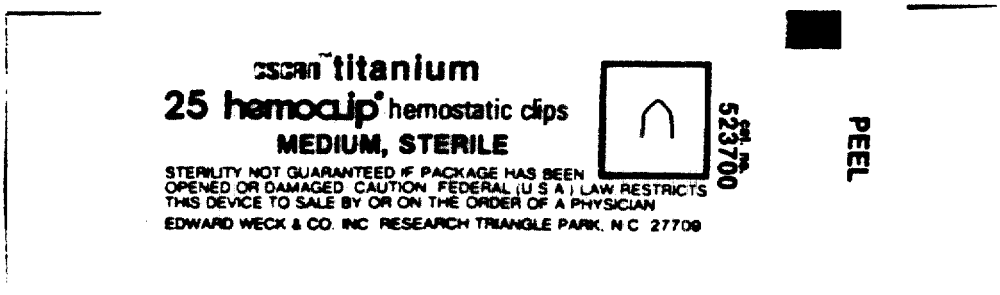
PROPOSED LABEL COPY: INDIVIDUAL CARTRIDGE LABELING



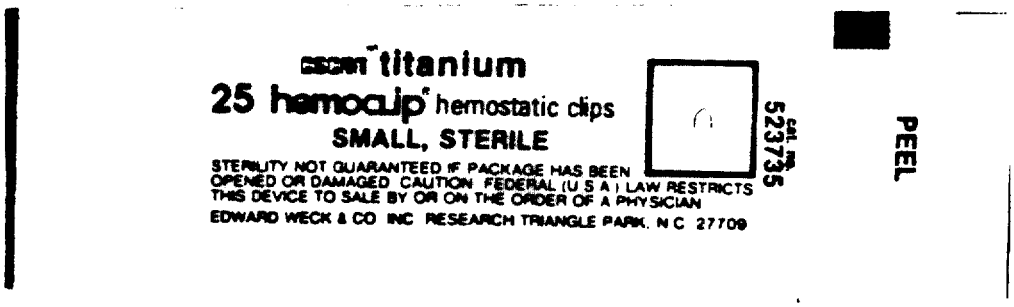
LARGE



MEDIUM-LARGE



MEDIUM



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Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

2 Statement of indications for use

INDICATIONS FOR USE

INDICATIONS FOR USE

Horizon ligating clips are indicated for procedures involving vessels or anatomic structures where ligating clips are the best choice. Select clip size, type and material based upon experience, judgement and needs.

✓ prescription device

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K982313

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2 Statement of indications for use

510(k) Number (if assigned): _____

Device Name: Hem-O-Lok™ ligating clips

INDICATIONS FOR USE

Weck Hem-O-Lok™ ligating clips are intended for use in procedures involving ligation of vessels or small tissue structures. Surgeons should select clip size based on experience, judgement and needs.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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3 Device description and engineering drawings

DEVICE DESCRIPTION
DEVICE DRAWINGS

DEVICE DESCRIPTION

The basic engineering design configuration of the clip and applier is unchanged from that provided in K941972.

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, Tenac® 5010.

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 [redacted] Sterilization will be performed at our contract sterilizer (B)(4) [redacted] using validated methods. The blister packs are fitted into an overpack carton which serves as the sales unit.

The corresponding clip applier is for endoscopic use and will be sold non-sterile. The applier is a reusable device. Instructions for cleaning and sterilizing the applier prior to use will be provided in the applier labeling. The applier is a class I device and is exempt from premarket notification 510(k) requirements (ref. 21 CFR 878.4300).

DEVICE DRAWINGS

Basic descriptive drawings of the clip and applier are included in this section.

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Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

(B)(4) Device Specifications

[redacted]

CLIP

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

(B)(4) Device Specifications

[redacted]

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

4 Premarket Notification Truthful and Accurate Statement

I certify that, in my position as Regulatory Affairs Manager of Weck Closure Systems, I believe to the best of my knowledge, that data and information submitted in this premarket notification is truthful and accurate and that relevant material facts have not been purposefully omitted.

Regulatory Affairs Manager
August 17, 1998

(510(k) number)

SS

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

5 Special Controls

MANDATORY PERFORMANCE STANDARDS

MANDATORY PERFORMANCE STANDARDS

To the best of our knowledge no performance standards have been established for this device under section 514 of the ACT.

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Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

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

See attached summary

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

WECK CLOSURE SYSTEMS

Premarket Notification [510(k)] Summary for 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 Weck's previous 510(k) filing number K941972.

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 (B)(4) [redacted]. (B)(4) Device S ifi ti The blister packs are fitted into an overpack carton which serves as the sales unit.

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Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

5. Intended Use of the Device

For use in procedures involving vessels or small tissue structures. Surgeons should select clip size based on experience, judgement, and needs.

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.

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

7 Comparison to Original Device

DEVICE TO WHICH EQUIVALENCE IS CLAIMED
COMPARISON OF SIMILARITIES AND DIFFERENCES

DEVICE TO WHICH EQUIVALENCE IS CLAIMED

The predicate device to which equivalence is claimed is Weck Hem-O-Lok™ ligating clips, K941972.

Pilling Weck, Inc. is listed as the sponsor of K941972. Pilling Weck split into two separate entities in 1997, Pilling Weck Surgical (surgical instruments) and Weck Closure Systems (ligation and other products). Weck Closure Systems is still at the One Weck Drive, Research Triangle Park, NC address identified in K941972.

COMPARISON OF SIMILARITIES AND DIFFERENCES

Weck has retained the original design without making any significant design or process modifications. This 510(k) is for the proposed labeling change described in detail in Section 1 of this submission.

Weck is including additional insignificant modifications which have occurred since K941972 was filed. These include:

(B)(4)

[redacted]

Ce o

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

8 Performance

DISCUSSION

DISCUSSION

Device performance will not be affected by the proposed change and therefore performance data is not included in this submission.

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Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

9 Biocompatability

TEST SELECTION
RESULTS

TEST SELECTION

The full intent of this change is provided in section 1 of this submission, i.e., a labeling change. Weck has not made significant modifications to the original Hem-o-Lok™ clip design or manufacturing process.

None-the-less, testing was performed to fully assure that there were no unanticipated biocompatibility issues as a result of the supplier change from (B)(4) [redacted] he trade name of the polyacetal material supplied by the new supplier (B)(4) Tenac 5010®.

The testing included in Table 2 and on the accompanying pages was performed in accordance with the requirements for permanent implants contacting tissue indicated in the FDA bluebook memo G95-1 "Use of International Standard ISO 10993, "Biological Testing of Medical Devices Part 1: Evaluation and Testing".

Table 2

	Cytoxicity	Sensitization	Irritation	Systemic toxicity (acute)	Subchronic toxicity (subacute)	Genotoxicity	Implantation	Haemocompatibility
G95-1 Tests	X	X	O	O	O	X	X	
Hem-o-Lok™ (Tenac™ 5010) tests performed	X	X	X	X		X	X	X

X - ISO evaluation tests for consideration
O - Additional tests which may be applicable

RESULTS

The specific tests performed and corresponding results are included by attachment. Results of testing confirm that Tenac® is biocompatible for its intended use.

ue

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

Table 1 - Initial Evaluation Tests for Consideration.*

(B)(4) Test Data

[redacted]

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

(B)(4) Test Data

(B)(4) Test Data

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(B)(4) Test Data

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

(B)(4) Test Data

[redacted]

TEST RESULT CERTIFICATE

(B)(4) Test Data

[redacted]

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

(B)(4) Test Data

[redacted]

TEST RESULT CERTIFICATE

(B)(4) Test Data

[redacted]

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

(B)(4) Test Data

[redacted]

TEST RESULT CERTIFICATE

(B)(4) Test Data

[redacted]

Questions Contact [redacted] at [redacted] or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

(B)(4) Test Data

[redacted]

TEST RESULT CERTIFICATE

(B)(4) Test Data

[redacted]

AMES - 1

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Environmental Sciences and Toxicology

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

Sponsor: Weck Closure Systems Group **Project Number:** (B)(4) [redacted]

(B)(4) Test Data

[redacted]

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AMES - 2

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

Sponsor: Weck Closure Systems Group **Project Number:** (B)(4) [redacted]

TABLE II

(B)(4) Test Data

[redacted]

AMES - 3

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

TABLE III

(B)(4) Test Data

[redacted]

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AMES - 4

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

Sponsor: Weck Closure Systems Group **Project Number:** (B)(4) [redacted]

TABLE IV

(B)(4) Test Data

[redacted]

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

(B)(4) Test Data

CHROMOSOMAL ABERRATION ASSAY IN CHINESE HAMSTER OVARY CELLS - ISO

Author

(B)(4)

FINAL REPORT DATE:
August 01, 1997

MANAGEMENT OF THE STUDY

(B)(4) Test Data

Sponsor:

Weck Closure Systems Group
Tall Pines Park
Jaffrey, NH 03452

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Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

(B)(4) Test Data

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6.0 Experimental Design

7.0 Dosage

8.0 Evaluation Criteria

9.0 Results

10.0 Conclusion

11.0 Records

12.0 Confidentiality Agreement

(B)(4) Test Data

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

(B)(4) Test Data

[redacted]

STUDY SUMMARY

(B)(4) Test Data

[redacted]

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Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

(B)(4) Test Data

[redacted]

STUDY DIRECTOR SIGNATURE AND VERIFICATION DATES

(B)(4) Test Data

[redacted]

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

(B)(4) Test Data

1.0 PURPOSE

(B)(4) Test Data

2.0 REFERENCES

(B)(4) Test Data

3.0 IDENTIFICATION OF THE TEST AND CONTROL ARTICLES

(B)(4) Test Data

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

(B)(4) Test Data

(B)(4) Test Data

4.0 IDENTIFICATION OF THE TEST SYSTEM

(B)(4) Test Data

5.0 JUSTIFICATION OF TEST SYSTEM AND ROUTE OF ADMINISTRATION

(B)(4) Test Data

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Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

(B)(4) Test Data

6.0 EXPERIMENTAL DESIGN

6.1 INDICATOR CELLS

(B)(4) Test Data

6.2 CONTROL ARTICLES

(B)(4) Test Data

6.3 TEST ARTICLE PREPARATION

(B)(4) Test Data

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

(B)(4) Test Data

[redacted]

6.4 CHROMOSOMAL ABERRATION ASSAY DESIGN

(B)(4) Test Data

[redacted]

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

(B)(4) Test Data

(B)(4) Test Data

7.0 DOSAGE

(B)(4) Test Data

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Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

(B)(4) Test Data

[redacted]

8.0 EVALUATION CRITERIA

(B)(4) Test Data

[redacted]

9.0 RESULTS

(B)(4) Test Data

[redacted]

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

10.0 CONCLUSION

(B)(4) Test Data

[redacted]

11.0 RECORDS

(B)(4) Test Data

[redacted]

12.0 CONFIDENTIALITY AGREEMENT

(B)(4) Test Data

[redacted]

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Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

(B)(4) Test Data

TABLE I

(B)(4) Test Data

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Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

(B)(4) Test Data

TABLE II

(B)(4) Test Data

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

(B)(4) Test Data

[redacted]

TABLE III

(B)(4) Test Data

[redacted]

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Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

(B)(4) Test Data

CHO/HGPRT FORWARD MUTATION ASSAY - ISO

(B)(4) Test Data

FINAL REPORT DATE:
July 8, 1997

(B)(4) Test Data

Sponsor:
Weck Closure Systems Group
Tall Pines Park
Jaffrey, NH 03452

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(B)(4) Test Data [redacted]

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

STUDY SUMMARY

(B)(4) Test Data

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(B)(4) Test Data

; Released by CDRH on 10/03/2017

STUDY DIRECTOR SIGNATURE AND VERIFICATION DATES

(B)(4) Test Data

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1.0 PURPOSE

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2.0 REFERENCES

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3.0 IDENTIFICATION OF THE TEST AND CONTROL ARTICLES

(B)(4) Test Data

(B)(4) Test Data

4.0 IDENTIFICATION OF THE TEST SYSTEM

(B)(4) Test Data

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

5.0 JUSTIFICATION OF TEST SYSTEM AND ROUTE OF ADMINISTRATION

(B)(4) Test Data [redacted]

6.0 EXPERIMENTAL DESIGN

(B)(4) Test Data [redacted]

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(B)(4) Test Data

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Released by CDRH on 10/03/2017

(B)(4) Test Data

[redacted]

(B)(4) Test Data

[redacted]

7.0 DOSAGE

(B)(4) Test Data

[redacted]

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

8.0 EVALUATION CRITERIA

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Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

TABLE [redacted] (B)(4) Test Data

(B)(4) Test Data

[redacted]

99

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

TABLE II. (B)(4) Test Data

(B)(4) Test Data

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

TABLE II ((B)(4) Test Data

(B)(4) Test Data

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

TABLE III

(B)(4) Test Data

(B)(4) Test Data

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Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

[redacted] SO

TABLE IV. [redacted] (B)(4) Test Data [redacted]

(B)(4) Test Data

[redacted]

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

TABLE V. [redacted] (B)(4) Test Data [redacted]

(B)(4) Test Data

[redacted]

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

TABLE V (c [redacted] **A** (B)(4) Test Data [redacted]

[redacted]

(B)(4) Test Data

[redacted]

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

st 2017-6482; Released by CDRH on 10/03/2017

(B)(4) Test Data

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TABLE VI

(B)(4) Test Data

Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(B)(4) Test Data

[redacted]

(B)(4) Test Data

[redacted]

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