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

DO NOT REMOVE THIS ROUTE SLIP!!!!

K-92-2186 6/1/92

FMN

FROM: LINVATEC ATTN: GLENN M. MATTEI P.O. BOX 12600 WECK DRIVE RESEARCH TRIANGLE PARK, NC 27709	LETTER DATE 02/14/92	LOGIN DATE 02/27/92	DUE DATE 08/30/92
	TYPE OF DOCUMENT: 510 (k) ST		CONTROL # K922186
SHORT NAME: LINVATEC	PHONE NO: 919-544-8000 ESTABLISHMENT NO: N		
TO: ODE/DMC	CONT. CONF.: N STATUS : R REV PANEL : SU PAN/PROD CODE(S): SU/ / /		FA
SUBJECT: HEM-O-LOK -- MODIFICATION	GDW AUG 6 1992		
DECISION: DECISION DATE: / /	RQST INFO DATE: 05/27/92 DATE: / / DATE: / / DATE: / / DATE: / / DATE: / /	INFO DUE DATE: 06/26/92 DATE: / / DATE: / / DATE: / / DATE: / / DATE: / /	

PRSB

SUPPLEMENT: 01 LTR DATE: 920529 LOGIN DATE: 920601

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
1390 Piccard Drive
Rockville, MD 20850

AUG 6 1992

Glenn M. Mattei, J.D.
Linvatec
P.O. Box 12600 Weck Drive
Research Triangle Park, North Carolina 27709

Re: K922186
Hem-O-Lok™
Regulatory Class: II
Dated: May 29, 1992
Received: June 1, 1992

Dear Dr. Mattei:

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and 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. In addition, the Food and Drug Administration (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 the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device.

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

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Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Division of Compliance Operations, Device Labeling Compliance Branch (HFZ-326) at (301) 427-1165. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Thomas J. Callahan for PRB

Paul R. Beninger, M.D.
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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

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DO NOT REMOVE THIS ROUTE SLIP!!!!

K-92-2186 5/14/92

From

FROM:	LETTER DATE	LOGIN DATE	DUE DATE
LINVATEC ATTN: GLENN M. MATTEI P.O. BOX 12600 WECK DRIVE RESEARCH TRIANGLE PARK, NC 27709	02/14/92	02/27/92	05/27/92
	TYPE OF DOCUMENT: 510 (k)		CONTROL # K922186
	PHONE NO: 919-544-8000		
SHORT NAME: LINVATEC	ESTABLISHMENT NO:		

TO:	
ODE/DMC	CONT. CONF.: N STATUS : R REV PANEL : SU PAN/PROD CODE(S): SU/ / /

DNC 5/27/92 HD

SUBJECT:
HEM-O-LOK

DECISION:	RQST INFO DATE:	INFO DUE DATE:
DECISION DATE: / /	DATE: / /	DATE: / /
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /
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	DATE: / /	DATE: / /

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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

Memorandum

Date 9/8/92

From REVIEWER(S) - NAME(S) Thomas Reynolds

Subject 510(k) NOTIFICATION K922186/A

To THE RECORD

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

90 (A) Is substantially equivalent to marketed devices.

_____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

_____ (C) Requires more data.

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

Additional Comments: see attached memo 7/31/92

Is this device subject to Postmarket Surveillance? Yes ☐ No ☒

This 510(k) contains: (check appropriate box(es))

☐ A 510(k) summary of safety and effectiveness, or

☒ A 510(k) statement that safety and effectiveness information will be made available

☐ The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

_____ No Confidentiality

_____ Confidentiality for 90 days

X Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class: Drug Indistable Stapler
79 GDW Class II
79 FZP Drug Indistable Clip Class III

Additional Product Code(s) w/Panel (optional):

REVIEW: Dionne Reneau (BRANCH CHIEF) | PRSB (BRANCH CODE) | 7-31-92 (DATE)

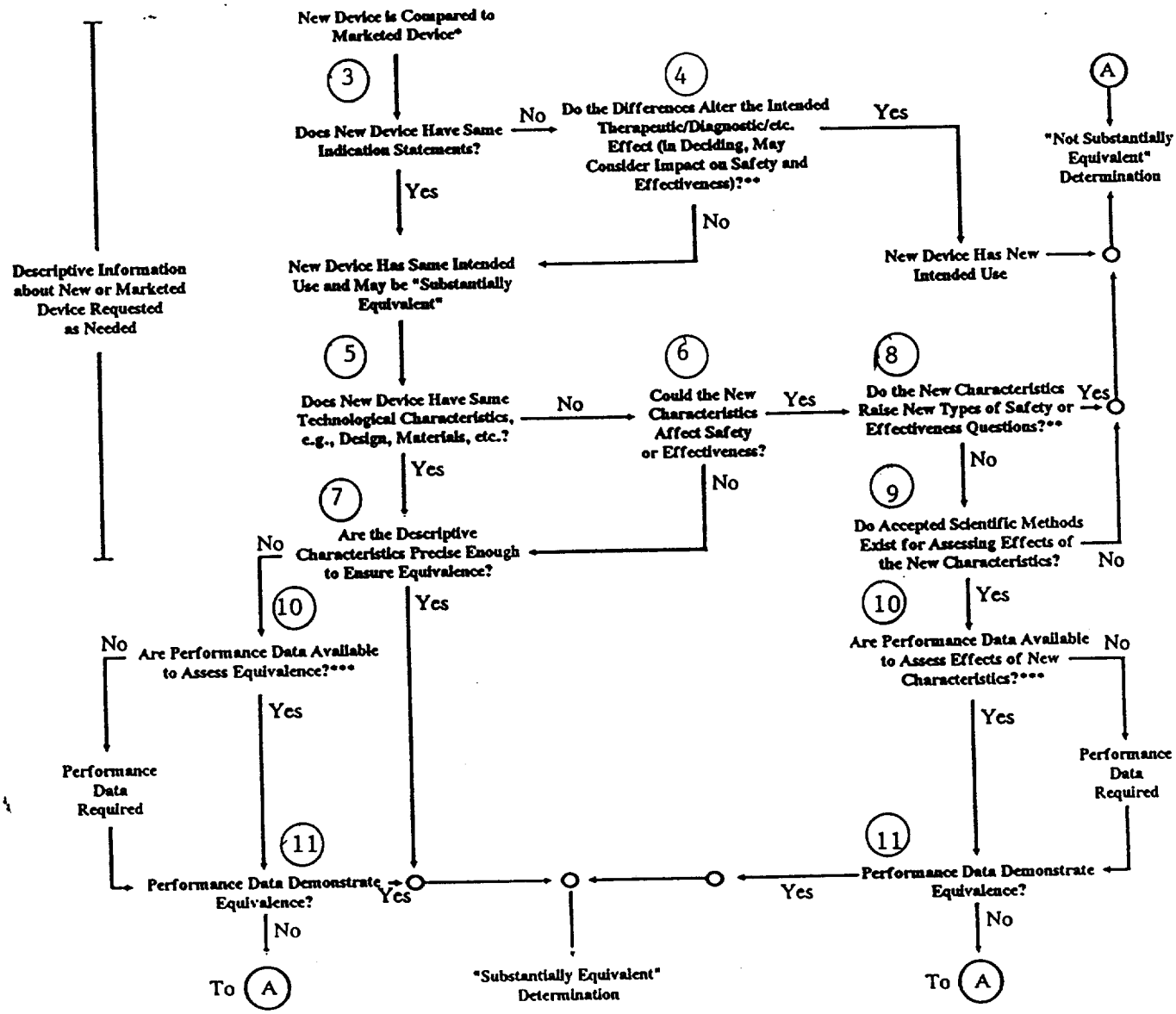
FINAL REVIEW: Thomas J. McCabe (DIVISION DIRECTOR) PRB 8/4/92 (DATE)

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

*DOES NOT APPLY TO ANY "SE" DECISIONS

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

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



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

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

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

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

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K 922186 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

REVIEWER: [illegible] DIVISION/BRANCH: DSRD/PRSB

TRADE NAME: ~~Hemo-Lok~~ (HL) Lysteny Clay COMMON NAME: Lysteny Clay

PRODUCT TO WHICH COMPARED: See K902108
(510(k) NUMBER IF KNOWN)

	YES	(NO)	
1. IS PRODUCT A DEVICE?	Y		- IF NO STOP
2. DEVICE SUBJECT TO 510(k)?	X		- IF NO STOP
3. SAME INDICATION STATEMENT?	Y		- 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?			

NOTE: IN ADDITION TO COMPLETING PAGE TWO, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR FOUR

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

MEMO TO THE RECORD
510(k) REVIEW
K922186

DATE: July 8, 1992
FROM: BIOLOGIST

OFFICE: HFZ-410
DIVISION: DGRD/PRSB

COMPANY NAME: Linvatec
DEVICE NAME: Hemo-Lok™ Clip and Appliers

1. **Critical Device ?** YES
2. **Implant (short-term or long-term)?** YES
3. **Software-driven?** N/A
4. **Device(s) to which equivalence is claimed and manufacturer:**
   The sponsor has claimed equivalence to itself, i.e., K902108

5. **Submission provides comparative specifications:** N/A
   comparative in vitro data: NO
   summary of animal testing: NO
   summary of clinical testing: NO

6. **Description of device and its differences from pre-enactment/predicate device(s), including indications for use, new technology and potential safety issues:** The sponsor has submitted a pre-market notification for the Hemo-Lok™ Ligating Clip and Appliers to notify the agency that the company intends to modify the sizes of the device currently available for market to include two additional clip and applier sizes that will encompass the currently marketed medium size as well as a small and large size. Dimensions for the new clips/appliers are as follows:

(b) (4) [redacted]

The devices are to be packaged in rigid plastic blisters with Tyvek™ coated lid. The products are to be marketed sterile, with the method of sterilization being ETO, the method of release biologic indicators, and the SAL 10^{-6}. Validation procedure information has been provided. The sponsor has also indicated that the ETO residue levels will be in compliance with levels currently recommended for devices of this nature.
Device labeling has been included; the product carries the following statements:
1. Hemo-Lok™ ligating clips are molded from a (b) (4) [redacted] material. This material allows permanent secure ligation while eliminating the possibility of radiological interference. and
2. Weck's Hemo-Lok™ is not intended for contraceptive tubal occlusion, but would be used to accomplish hemostasis after transection of the fallopian tube.

7. **Recommendation:** Based on my review of the information contained in this submission, I recommend a finding of substantial

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

equivalence for this device.

8. Classification: 79GDW, Implantable Staple, Class II

Frances Moreland Curtis, M.S.B.
Plastic and Reconstructive Surgery Branch
Division of General and Restorative Devices

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)
1390 Piccard Drive
Rockville, Maryland 20850

JUNE 1, 1992

LINVATEC
ATTN: GLENN M. MATTEI
P.O. BOX 12600 WECK DRIVE
RESEARCH TRIANGLE PARK, NC 27709

510(k) Number: K922186
Received: 06-01-92
Product: HEM-O-LOK -- MODIFICATION

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. 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 one above 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.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so within 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Chief, Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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

Edward Weck Incorporated

Edward Weck Incorporated
P.O. Box 12600
Weck Drive
Research Triangle Park, NC 27709
(919) 544-8000

WECK
A Squibb Company

July 8, 1992
VIA RAPIFAX

Ms. Francis Mooreland-Curtis
FOOD AND DRUG ADMINISTRATION
National Control for Devices & Radiological Health
Document Control Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

RE: Addendum to K922186

Dear Ms. Mooreland-Curtis:

Please include the statement below to our 510(k) K922186.

"Weck certifies that safety and effectiveness information supporting an equivalency determination for this device will be made available to interested parties upon request."

Sincerely,

Glenn M. Mattei, J.D.

GMM/jh

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

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K922186/A

Weck Endoscopy
P.O. Box 12600 Weck Drive Research Triangle Park, NC 27709 919 544-8000

May 29, 1992

RECEIVED
1 JUN 92 11 32
FDA/CDRH/ODE/DMC

Ms. Francis Mooreland-Curtis
FOOD AND DRUG ADMINISTRATION
National Control for Devices & Radiological Health
Document Control Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

RE: 922186

Dear Ms. Mooreland-Curtis,

On 5/27/92 I received a telephone call from your office concerning our submission of a large size Hem-O-Lok™ clip. You informed me that the submission would be considered under a new 510(K) number and asked for further information. I believe I have addressed your questions below.

1. Question: Will the contraindication for tubal ligation be included in the label copy?

   Answer: We will contraindicate for tubal ligation in our packaging insert (see Attachment #1).

2. Question: How will the product be sterilized and validated?

   Answer: The product will be packaged in a rigid plastic blister and Tyvek coated lidding. It will be sterilized by Ethylene Oxide. As the large and small products are equivalent to the medium size, only one half cycle will be used to validate the product (see Attachment 2 & 3). Please refer to our original validation of this product (see Attachment 3). The product's SAL is 10^{-6}.

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

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

3. Question: Please include the safety and effectiveness information or the standard statement.

Answer: Weck certifies that information supporting an equivalency determination will be available for this device upon request.

If you have any further questions, please let me know.

Sincerely,

Glenn M. Mattei, J.D.

GMM/jh

Attachments

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

Attachment 1

Packaging Insert

The packaging insert will be substantially similar to that below.

HEM-O-LOK™ LIGATING CLIPS AND APPLIERS

DESCRIPTION

Hem-O-Lok™ ligating clips are molded from a non-absorbable plastic material. This material allows permanent secure ligation while eliminating the possibility of radiological interference. The clips are supplied sterile.

WARNINGS

The clip should be used only with the Hem-O-Lok™ clip applier of the appropriate size.

Do not resterilize the clips or the clip cartridge.

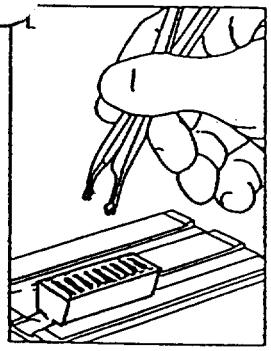
Weck's Hem-O-Lok™ is not intended for contraceptive tubal occlusion, but would be used to accomplish hemostasis after transection of the fallopian tube.

PRECAUTIONS

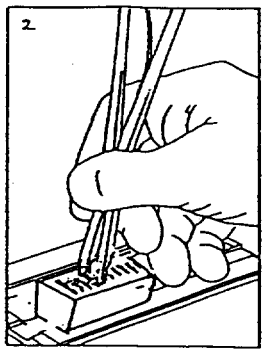
The clip must be latched to ensure proper ligation of the vessel or tissue

Tissue must be compliant enough to allow latch to engage securely. Depending on the toughness of the tissue, the latch may not attenuate the tissue enough to latch. Some dissection of tissue from vessel surface may be necessary in some circumstances.

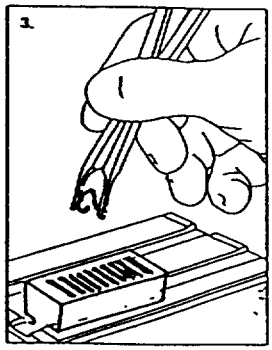
STRUCTIONS FOR USE



Grasp applier in box lock area using pencil grip technique.



Insert jaws of instrument into cartridge slot making sure the tips of the applier are perpendicular to the surface of the cartridge. Applier should be inserted firmly until it stops.



Withdraw applier from cartridge. The clip design provides secure contact between the clip and the applier. Therefore, the clip will remain securely in the applier during transfer without maintaining tension on the ring handles.

4. The applier with the clip in the jaws, is ready to be passed to the surgeon.
5. The clip is applied by closing the instrument until there is an audible and tactile locking response. In areas where some tissue surrounds the vessel, there may be no audible or tactile feedback. In all cases the surgeon should verify closure and hemostasis.
6. The interlock locking feature of the clip will securely hold the closed clip on the vessels and tissue. The instrument is opened by relieving the closing force and can be smoothly withdrawn from the ligation site when fully opened.
7. If clip removal is desired, grasp opposing legs of clip and twist apart or cut the clip at the hinge.

WECK
A Squibb Company

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

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ATTACHMENT # 2

	INSTALLATION QUALIFICATION	PERFORMANCE QUALIFICATION	PROCEDURE
PRODUCT CHANGE			
New Product		☐	Section 3.2, 4.0
Existing Product		☑	Section 3.2.1.1, 3.2.1.2.1, 3.2.1.2.3, 4.3.1.1, 4.5.2.1, 4.5.4
New packaging		☐	Section 3.2, 4.0
Existing packaging		☑	Section 3.2.1.1, 3.2.1.2.1, 3.2.1.2.3, 4.3.1.1, 4.5.2.1.1, 4.5.4
Change in Manufacturing facility		☐	Section 3.2.1.1
Change in Manufacturing process		☐	Section 3.2.1.1
CONTROL CHANGE			
New Controls (no effect on process cycle)	☐		Section 2.1, 2.2
New controls (effect on process cycle)	☐	☐	All
Measurement device change	☐		Section 2.1
VESSEL HARDWARE CHANGE			
Total change (i.e. plumbing station, gas volitolizer)	☐	☐	All
Partial change (no effect on process cycle)	☐		Section 2.0
Partial change (effect on process cycle)	☐	☐	All
PROCESS CHANGE			
Change in process parameters		☐	Section 3.0
OTHER			

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

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ATTACHMENT #2

STERILIZATION CHANGE CONTROL PROTOCOL

Written by: [signature] Date: 5-27-92

Reviewed by: Warren Wilson Manager Q.A./Q.C. Date: 5-27-92

Reviewed by: [signature] FOR FREDDY CANADA Manager Manufacturing Date: 5/27/92

CHANGE: The Hemo-lock product will be extended to include a small and a large ligating clip.

PROCEDURE: (b) (4)

RESULTS:

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

(b) (4)

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TITLE:

STERILIZATION PROGRAM VALIDATION AND CHANGE CONTROL

SCOPE:

This procedure is to be reviewed when any aspect of the ethylene oxide sterilization program is planned for revision.

PURPOSE:

The purpose of this procedure is to define the recommended practices for validation of the Ethylene Oxide production sterilization process. This procedure is based on industry standards and is intended to standardize the validation program at Edward Weck Inc.

This procedure is to be used as a reference for any change to the sterilization process, product, packaging, ancillary equipment or manufacturing facility. Possible changes are included in this text along with the level of validation required. When a situation occurs which is not covered in this procedure an interdisciplinary review will be performed and a qualification protocol developed.

PROCEDURE:

1.0 Change Control Checklist and Protocol

(b) (4) [redacted]

2.0 Installation Qualification

2.1 Calibration

(b) (4) [redacted]

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

(b) (4)

(b) (4)

(b) (4) Testing

(b) (4)

(b) (4) Testing

(b) (4) Testing

[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

	INSTALLATION QUALIFICATION	PERFORMANCE QUALIFICATION	PROCEDURE
PRODUCT CHANGE			
New Product		☐	Section 3.2, 4.0
Existing Product		☐	Section 3.2.1.1, 3.2.1.2.1, 3.2.1.2.3, 4.3.1.1, 4.5.2.1, 4.5.4
New packaging		☐	Section 3.2, 4.0
Existing packaging		☐	Section 3.2.1.1, 3.2.1.2.1, 3.2.1.2.3, 4.3.1.1, 4.5.2.1.1, 4.5.4
Change in Manufacturing facility		☐	Section 3.2.1.1
Change in Manufacturing process		☐	Section 3.2.1.1
CONTROL CHANGE			
New Controls (no effect on process cycle)	☐		Section 2.1, 2.2
New controls (effect on process cycle)	☐	☐	All
Measurement device change	☐		Section 2.1
VESSEL HARDWARE CHANGE			
Total change (i.e. plumbing station, gas volitolizer)	☐	☐	All
Partial change (no effect on process cycle)	☐		Section 2.0
Partial change (effect on process cycle)	☐	☐	All
PROCESS CHANGE			
Change in process parameters		☐	Section 3.0
OTHER			

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

STERILIZATION CHANGE CONTROL PROTOCOL

Written by: _____ Date: _____

Reviewed by: _____ Manager Q.A./Q.C. Date: _____

Reviewed by: _____ Manager Manufacturing Date: _____

CHANGE:

PROCEDURE:

RESULTS:

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

ATTACHMENT #4

STERILIZATION CHANGE CONTROL PROTOCOL

Written by: Dan Leavitt Date: 2/26/90

Reviewed by: Dan Leavitt Manager Q.A./Q.C. Date: 2/26/90

Reviewed by: [signature] Manager Manufacturing Date: 3/2/90

CHANGE:

Qualification for new product - Hemo-lock.

PROCEDURE:

See attached protocol.

RESULTS:

See attached results.

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

ATTACHMENT # 4

	INSTALLATION QUALIFICATION	PERFORMANCE QUALIFICATION	PROCEDURE
PRODUCT CHANGE			
New Product		☒	Section 3.2, 4.0
Existing Product		☐	Section 3.2.1.1, 3.2.1.2.1, 3.2.1.2.3, 4.3.1.1, 4.5.2.1, 4.5.4
New packaging		☐	Section 3.2, 4.0
Existing packaging		☐	Section 3.2.1.1, 3.2.1.2.1, 3.2.1.2.3, 4.3.1.1, 4.5.2.1.1, 4.5.4
Change in Manufacturing facility		☐	Section 3.2.1.1
Change in Manufacturing process		☐	Section 3.2.1.1
CONTROL CHANGE			
New Controls (no effect on process cycle)	☐		Section 2.1, 2.2
New controls (effect on process cycle)	☐	☐	All
Measurement device change	☐		Section 2.1
VESSEL HARDWARE CHANGE			
Total change (i.e. plumbing station, gas volitolizer)	☐	☐	All
Partial change (no effect on process cycle)	☐		Section 2.0
Partial change (effect on process cycle)	☐	☐	All
PROCESS CHANGE			
Change in process parameters		☐	Section 3.0
OTHER			

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

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Procedure:

(b) (4) Testing

[redacted]

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

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Results

(b) (4) Testing

[redacted]

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

(b) (4) Diagrams

(b) (4) Diagrams

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DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

MAY 27, 1992

LINVATEC
ATTN: GLENN M. MATTEI
P.O. BOX 12600 WECK DRIVE
RESEARCH TRIANGLE PARK, NC 27709

510(k) Number: K922186
Product: HEM-O-LOK -- MODIFICATION

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

If after 30 days the requested information is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Chief, Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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

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DO NOT REMOVE THIS ROUTE SLIP!!!!

K-92-2186

5/27/92

FROM:	LETTER DATE	LOGIN DATE	DUE DATE
LINVATEC ATTN: GLENN M. MATTEI P.O. BOX 12600 WECK DRIVE RESEARCH TRIANGLE PARK, NC 27709	02/14/92	02/27/92	05/27/92
	TYPE OF DOCUMENT: 510 (k)		CONTROL # K922186
	PHONE NO: 919-544-8000		
SHORT NAME: LINVATEC	ESTABLISHMENT NO:		

TO:	
ODE/DMC	CONT. CONF.: N STATUS : H REV PANEL : SU PAN/PROD CODE(S): SU/ / /

SUBJECT:
HEM-O-LOK -- MODIFICATION

DECISION:	RQST INFO DATE: 05/27/92	INFO DUE DATE: 06/26/92
DECISION DATE: / /	DATE: / /	DATE: / /
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /

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

Memorandum

Date 5/27/92

From REVIEWER(S) - NAME(S) Bruce Manlove

Subject 510(k) NOTIFICATION K922186

To THE RECORD

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

_____ (A) Is substantially equivalent to marketed devices.

_____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

__^__ (C) Requires more data.

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

Additional Comments: See attached memo 5/27/92 mc

Is this device subject to Postmarket Surveillance? Yes ☐ No ☐

This 510(k) contains: (check appropriate box(es))

☐ A 510(k) summary of safety and effectiveness, or

☐ A 510(k) statement that safety and effectiveness information will be made available

☐ The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

_____ No Confidentiality

_____ Confidentiality for 90 days

_____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class:

_____

Additional Product Code(s) w/Panel (optional):

_____

REVIEW: _____ (BRANCH CHIEF) BRANCH CODE _____ (DATE)

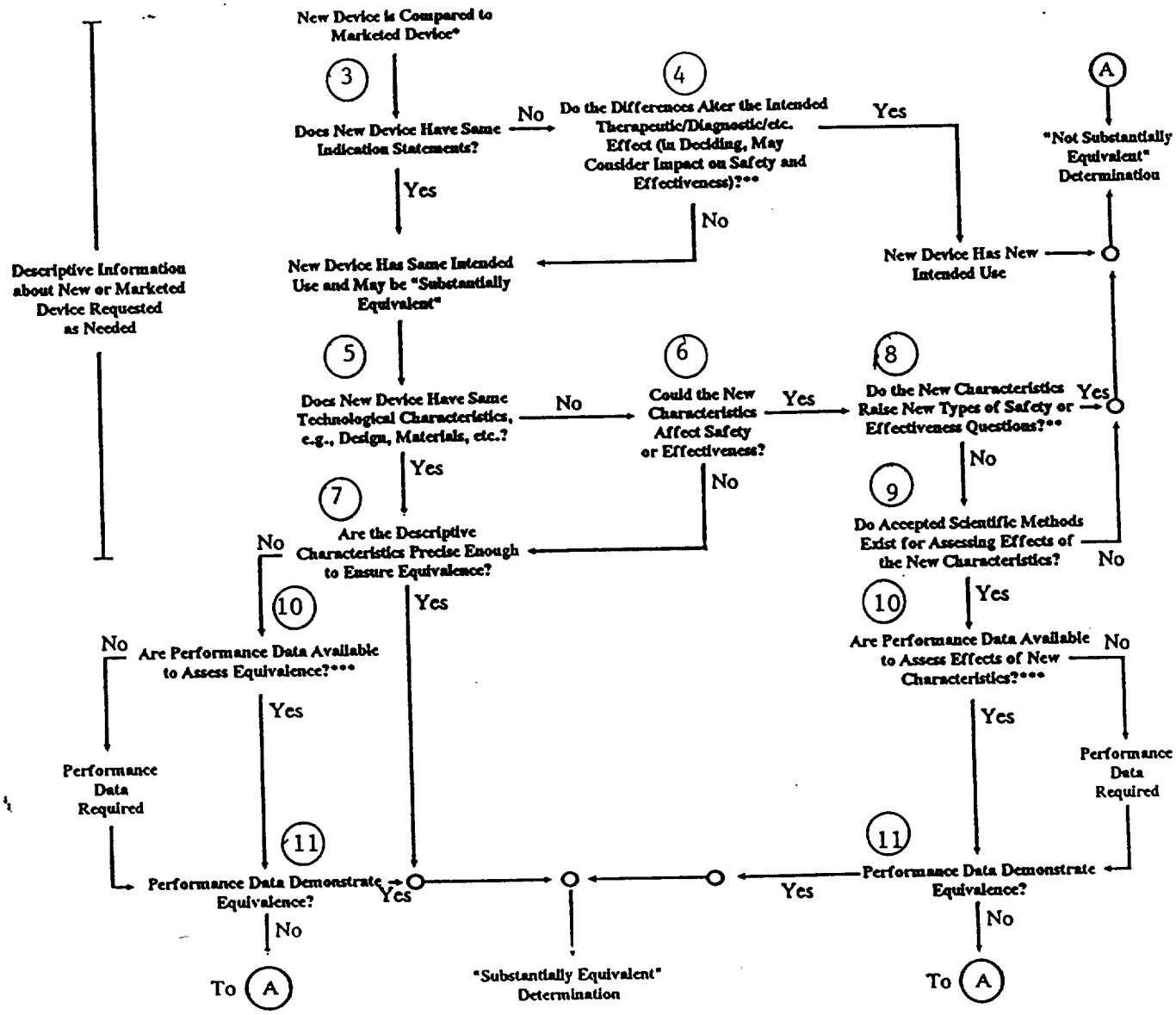
FINAL REVIEW: _____ (DIVISION DIRECTOR) _____ (DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS

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

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

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



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

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

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

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MEMO TO THE RECORD

DATE: May 26, 1992
FROM: BIOLOGIST

OFFICE: HFZ-410
DIVISION: DSRD/SDB

RE: K922186
Hem-O-Lok™
Linvatec/Weck, Inc

The sponsor has submitted a pre-market notification informing the agency that they intend to market 2 additional sizes of their ligating clip. Previously, the sponsor had submitted a 510(K) for a device that was erquipped with medium clips only(K902108). They have submitted device dimensions for the proposed clip sizes with this request.
The sponsor is to be contacted and requested to provide current device labeling for this product-he will be specifically requested to further modify the device labeling by including the following contraindication statement:

"This device is not intended for contraceptive tubal occlusion, but may be used to achieve hemostasis following transection of the fallopian tube."

In addition, he will be requested to actual sterility information.

He will also be reminded of the requirements of the SMDA act, i.e. that he must provide either the statement concerning the provision of information upon request to interested parties etc., OR a 510(K) summmary of safety and effectivenss for the device.

Frances Moreland Curtis

Frances Moreland Curtis, M.Sc.B

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)
1390 Piccard Drive
Rockville, Maryland 20850

MAY 14, 1992

LINVATEC
ATTN: GLENN M. MATTEI
P.O. BOX 12600 WECK DRIVE
RESEARCH TRIANGLE PARK, NC 27709

510(k) Number: K922186
Received: 02-27-92
Product: HEM-O-LOK

We have 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.

The Safe Medical Devices Act of 1990 (SMDA), signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so within 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date, you may want to check with FDA to determine the status of your submission.

In addition, the SMDA requires all persons submitting a premarket notification submission to include either (1) a summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based (510(k) summary), OR (2) a statement that safety and effectiveness information will be made available to interested persons upon request (510(k) statement). Safety and effectiveness information refers to information in the premarket notification submission, including adverse safety and effectiveness information, that is relevant to an assessment of substantial equivalence. The information could be descriptive information about the new and predicate device(s), or performance or clinical testing information. We cannot issue a final decision on your 510(k) unless you comply with this requirement.

Although FDA acknowledges that the law provides the 510(k) submitter an alternative, FDA encourages manufacturers to provide a 510(k) statement to FDA and to make their safety and effectiveness information available to the public, excluding confidential manufacturing process information, in lieu of submitting a 510(k) summary to the agency until FDA promulgates a regulation on the content and format of 510(k) summaries. **Since the law**

1 of 7

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

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requires that FDA must make the 510(k) summary, or the source of information referred to in the 510(k) statement, publicly available within 30 days of making a substantial equivalence determination, we advise you that we may no longer honor any request for extended confidentiality under 21 CFR 807.95.

Additionally, the new legislation also requires any person who asserts that a device is substantially equivalent to a class III device to (1) certify that he or she has conducted a reasonable search of all information known, or otherwise available, about the generic type of device, AND (2) provide a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description (class III summary and certification). The description should be sufficiently comprehensive to demonstrate that an applicant is fully aware of the types of problems to which the device is susceptible. If you have not provided this class III summary and certification in your premarket notification, please provide it as soon as possible. We cannot complete the review of your submission until you do so.

Furthermore, the new legislation, section 522(a)(1), of the Act, states that if your device is a permanent implant the failure of which may cause death, you may be subject to required postmarket surveillance. If the premarket notification for your device was originally received on or after November 8, 1991, is subsequently found to be substantially equivalent to an Aneurysm Clip, Annuloplasty Ring, Artificial Embolization Device, Automatic Implanted Cardioverter Defibrillator System, Cardiovascular Intravascular Filter, Cardiovascular Permanent Pacemaker Electrode (Lead), Central Nervous System Fluid Shunt, Coronary Vascular Stent, Implantable Pacemaker Pulse Generator, Implanted Diaphragmatic/Phrenic Nerve Stimulator, Intracardiac Patch or Pledget, Intravascular Occluding Catheter, Replacement Heart Valve, Total Artificial Heart, Tracheal Prosthesis, Vascular Graft Prosthesis (less than 6 mm diameter), Vascular Graft Prosthesis (6 mm or greater diameter), Vena Cava Clip, or Ventricular Assist Device - Implant, you will be subject to the required postmarket surveillance and so notified of this determination in your substantially equivalent letter. (Some of the above listed types of devices may require a premarket approval application). This list is subject to change without notification. If you have any questions as to whether or not your device may be subject to postmarket surveillance or about this program, please contact the Postmarket Surveillance Studies Branch at (301) 227-8639.

Please note that the SMDA may have additional requirements affecting your device. You will be informed of these requirements as they become effective.

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.

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

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If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Chief, Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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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 & HUMAN SERVICES Public Health Service

Memorandum

rcvd 5/4/92

Date 2-28-92

From Jessica S. Lewis, Clerk-Typist (CDRH, ODE, DMC) HFZ-401

Subject Premarket Notification Number(s) K902108

To Division Director SURGERY

The attached information has been received by the 510(K) Document Mail Center (DMC), on the above referenced 510(K) file(s). Since a final decision has been rendered, the record is officially closed.

Please review the document(s) and return to DMC directed to my attention, with one of the statements checked below. Feel free to note any additional comments below. If there are any questions, please contact me on 427-1027. Thank you for your cooperation.

~~X Information does not change status of 510(K); no other action required by DMC; please file. The Division should prepare a confirmation letter - example attached.~~

X Additional information requires a new 510(K); please process.

Comments: [illegible]

This information should be returned by MARCH 13, 1992.

Reviewed by:

Panel: 79 Date: 5/6/92

Attachment

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

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DMS confirmation letter

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Re: Device Name
Dated: Feb 14, 1992
Received: February 27, 1992

Dear Dr. Mueller:

We have reviewed the information dated February 14, 1992 regarding the 510(k) notification (K902108) previously submitted for the device referenced above. Based solely on the information that you have provided, it does not appear that you have significantly changed or modified the design, components, method of manufacture, or intended use of the device referenced above (see 21 CFR 807.81(a)(3)). It is, however, your responsibility to determine if the change or modification to the device or its labeling could significantly affect the device's safety or effectiveness and thus require submission of a new 510(k). The information you have supplied will be added to the file.

If you have any questions regarding the contents of this letter, please contact Donna Bezdikian at (301) 427-2090

Sincerely yours,

Division Director
Division of _____
Office of Device Evaluation
Center for Devices and
Radiological Health

ND
(please do
previous
a 510(K)
thank

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

Linvatec

K922186

Weck Endoscopy
P.O. Box 12600 Weck Drive Research Triangle Park, NC 27709 919 544-8000

February 14, 1992

RECEIVED
27 FEB 92 12 58
FDA/DRH/ODE/DMC

Food and Drug Administration
National Center for Devices & Radiological Health
Document Control Center (HFZ 401)
1390 Piccard Drive
Rockville, MD 20850

Dear FDA Administrator:

I am writing this correspondence to request an amendment to K902108, Hem-O-Lok™. In 1990 you reviewed this application. On 8/6/90 it was found to be substantially equivalent.

At the time of submission we included the medium size in our application. We have since determined other sizes are needed. We would like to market a small size and a large size.

The following information describes changes, if any, to our original submission:

Name - The same.

Catalog Number - (b) (4) [redacted]

Classification - The same.

Labeling/Advertisements - The same.

Drawings - See attached drawings of the clips.

Material - The same.

Sterilization - The SAL is same as is the method and parameters.

Efficacy and Safety - There are no efficacy or safety problems.

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

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(b) (4) [redacted] s the addition (b) (4) [redacted] Therefore, we request that the 510(K) #K902108 be amended to add these additional sizes.

Sincerely,

Glenn M. Mattei, J.D.

GMM/jh

Attachments

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

(b) (4) Diagrams

(b) (4) Diagrams