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

AUG 1 4 2002

K021808

## PART 9
## SUMMARY OF SAFETY AND EFFECTIVENESS

# 510(k) SUMMARY

Pursuant to §513(i)(3)(A) of the Food, Drug, and cosmetic Act, Weck submits this summary of safety and effectiveness.

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

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

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

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

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

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

4. **Description of the Device**

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

5. **Intended Use of the Device**

Weck Hem-o-lok Automatic Ligating Clip Appliers are indicated for use as delivery devices for Hem-o-lok non-absorbable polymer ligating clips. Hem-o-lok ligating clips are intended for use in procedures involving ligation of vessels or tissue structures.


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



Surgeons should apply the appropriate size clip for the size of the vessel or tissue structures to be ligated such that the clip completely encompasses the vessel or tissue structure.

6. **Summary of Technological Characteristics**

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

Questions Contact FDA/CDRH/DID at CDRHFOISTATUS@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
9200 Corporate Boulevard
Rockville MD 20850

AUG 14 2002

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

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

Dear Mr. Lucky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

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

K021808

**PART 7**
**INDICATION FOR USE**

# Statement of Indications For Use

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

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

Weck Hem-o-lok Automatic Ligating Clip Appliers are indicated for use as delivery devices for Hem-o-lok non-absorbable polymer ligating clips. Hem-o-lok ligating clips are intended for use in procedures involving ligation of vessels or tissue structures. Surgeons should apply the appropriate size clip for the size of the vessel or tissue structures to be ligated such that the clip completely encompasses the vessel or tissue structure.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

| | | |
|---|---|---|
| Prescription Use<br>(Per 21 CRF 801.109) | OR | Over-The-Counter Use<br>(Optional Format 1-2-96) |

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

**510(k) Number** K021808



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
9200 Corporate Boulevard
Rockville MD 20850

AUG 14 2002

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

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

Dear Mr. Lucky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

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

K021808

**PART 7**
**INDICATION FOR USE**

# Statement of Indications For Use

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

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

Weck Hem-o-lok Automatic Ligating Clip Appliers are indicated for use as delivery devices for Hem-o-lok non-absorbable polymer ligating clips. Hem-o-lok ligating clips are intended for use in procedures involving ligation of vessels or tissue structures. Surgeons should apply the appropriate size clip for the size of the vessel or tissue structures to be ligated such that the clip completely encompasses the vessel or tissue structure.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

| | | |
|---|---|---|
| Prescription Use<br>(Per 21 CRF 801.109) | OR | Over-The-Counter Use<br>(Optional Format 1-2-96) |

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

**510(k) Number** K021808



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 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

June 03, 2002

WECK
CLOSURE SYSTEM
2917 WECK DR.
DURHAM, NC 27709
ATTN: JAMES LUCKY

510(k) Number: K021808
Received: 03-JUN-2002
Product: WECK HEM-O-LOK AUTOMATIC LIGATING CLIP APPLIER

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

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

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the DMC will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh.ode/A02-01.html.

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

Sincerely yours,

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



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

K021808

RECEIVED

JUN 3 10 46 AM '02

FDA/CDRH/ODE/DMC

**WECK®**
*A Teleflex Company*

May 31, 2002

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

**Subject:** **510(k) for Hem-o-lok™ Automatic Clip Appliers**

Dear Sir/Madam:

According to Section 510(k) of the Federal Food, Drug and Cosmetic Act, and in conformance with 21 CFR §807 Subpart E, Weck submits this premarket notification to introduce into commercial distribution the Hem-o-lok™ Automatic Clip Applier (hereinafter referred to as the proposed automatic applier). The proposed automatic applier is designed for delivery of Hem-o-lok non-absorbable polymer clips for ligation of vessels and tissue structures.

The clips delivered by the proposed automatic applier described in this submission are substantially equivalent in design, materials, manufacturing and intended use to Weck Hem-o-lok clips which received marketing clearance under: **K902108** (Original submission, medium size clips); **K922186** (addition of small and large size clips); **K941972** (change in ownership); **K982941 and K982944** (change in materials and labeling); **K993157** (change to indications and contraindications); and **K003337** (promotion for specific operating procedures).

The delivery mechanism of the proposed automatic applier is substantially equivalent to the following legally marketed predicate devices: **K883018** (U.S.S.C. AutoSuture Endoclip 5mm Disposable Clip Applier); and Weck reusable ligating clip appliers. The Weck reusable applier is a legally marketed predicate which is exempt from premarket notification requirements under **21 CFR 878.4800**.

This submission is being provided in duplicate and includes a statement of indications for use for the proposed device. Should you have any questions, please contact me at **919.361.4041.**

Sincerely,

James Lucky
V.P., Regulatory Affairs and Quality Assurance

SK8

18

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 of Contents



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

# PART 1
## GENERAL INFORMATION

**The following information is being submitted in conformance with 21 CFR §807.87:**

**Submission Type:** Traditional 510(k)

**Applicant or Sponsor:** Weck Closure Systems (Address and contact information provided below)

| | |
|---|---|
| A) **Device Classification Name**: | Implantable clip – 79FZP,<br>Regulation number: 878.4300 |
| **Common/Usual Name:** | Ligating clip |
| **Trade/Proprietary Name:** | Weck Hem-o-lok® Automatic Ligating Clip Applier |
| B) **Establishment Registration: Numbers and Addresses:** | **Manufacturer**: 1044475<br>Weck Closure Systems<br>2917 Weck Drive<br>Research Triangle Park, NC 27709<br>Contact: Brian Young, Sr. Regulatory Manager<br>Phone: 919.361.4041<br>FAX: 919.361.3914<br>e-mail: byoung@wecksurgical.com<br><br>**Contract Sterilizer:** (b) (4) [redacted]<br>(b) (4) [redacted] |
| C) **Device Classification:** | Class II |
| **Device Panel:** | General and Restorative Devices (DGRND) |
| D) **Performance Standards:** | No performance standards applicable to this product have been established by the Food and Drug Administration. |
| E) **Device Description:** | Complete device description, including drawings are enclosed in **Part 2**; |
| **Proposed Labeling:** | Draft labels and instructions for use for the proposed device are contained in **Part 3**; |
| F) **Statement Of Substantial Equivalence:** | A statement of substantial equivalence is provided in **Part 4**; |



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

20

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



| | |
|---|---|
| G) **Product Testing:** | Supporting data to show that the proposed device has no adverse effect on safety and effectiveness are provided in **Part 5**; a statement regarding packaging and sterilization is provided in **Part 6**; |
| H) **Summary Of Safety And Effectiveness:** | A summary of safety and effectiveness is provided in **Part 9**; |
| I) **Financial Certification / Disclosure:** | There are no clinical data included in this submission therefore financial disclosure requirements do not apply. |
| J) **Class III Summary:** | Substantial equivalence to a device which has been classified into class III is not being claimed. |
| K) **Truthful and Accuracy Statement:** | Provided in **Part 8**. |
| **Indication For Use:** | Provided in **Part 7**. |

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

# PART 2
# DEVICE DESCRIPTION

## 1. INTRODUCTION

The proposed device is a sterile, single use, automatic clip applier containing 15 Hem-o-lok polymer ligating clips and a bright orange last clip lockout/indicator. The automatic applier is a delivery device for applying Hem-o-lok non-absorbable polymer ligating clips cleared by FDA under 510(k) number K902108. The clip is intended to effectuate hemostasis by vessel ligation.

## 2. GENERAL DEVICE CHARACTERISTICS

The proposed automatic applier consists of a handle, shaft containing 15 locking polymer clips, and jaw. The major functions of the device are clip feeding, approximation (positioning the clip around the vessel), and closure. The applier is discarded after the surgical procedure whereas the applied non-absorbable clips remain in the patient.

Two models of the proposed device will be available. The first model is intended for endoscopic application of medium large size clips, and employs a pistol-grip handle (catalog number 543965). The overall length of the endoscopic device is 44 cm (17.3 inches) with a working length of 29.7 cm (11.7 inches). The endoscopic device is designed for use down a 5 mm cannula and includes a knob to allow 360° rotation of the applier shaft for jaw positioning using the index finger of the gripping hand. The second model is intended for open surgery application of large size clips, and employs a ring handle scissor-type grip (catalog number 543181). The overall length of the open surgery device is 35 cm (13.8 inches) with a working length of 20.1 cm (7.9 inches). **Figures 1 and 2** provide engineering assembly drawings of the two models. **Figure 3** provides an illustration of the Hem-o-lok clip in the open and closed position.

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

**PART 2**
**DEVICE DESCRIPTION**

### 3. COMPONENTS AND MATERIALS

The following assembly process narrative is provided for the endoscopic model. A similar assembly process will be employed for the open surgery model.

(b) (4)

[redacted]

**Table 1** provides a list of components and materials used in the two models. Biocompatibility testing of materials with patient contact is included in **Part 5**.

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



23

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



(b) (4)

[redacted]

Figure 1 – Assembly Drawing of Open Model

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)

[redacted]

Figure 2 – Assembly Drawing of Endoscopic Model

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



Open position

Closed Position


A. 5.5 mm (Medium-Large, Endo)
7.3 mm (Large, Open)

B. 7 mm (Endo)
10mm (Open)

Figure 3 - Clip Drawings

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:** Materials List

| Component Information | | | Material Information | ISO Patient Contact[22] | Test Recommended per | Biocompatibility Test References | Model (Open or Endo) |
|---|---|---|---|---|---|---|---|
| Component Name | Qty | Component # | | | | | |
| [redacted] | | | | | | | |

(b) (4)



27

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



| Component Information | | | Material Information | ISO Patient Contact[22] | Test Recommended per 10993-1 | Biocompatibility Test References | Model (Open or Endo) |
|---|---|---|---|---|---|---|---|
| Component Name | Qty | Component # | | | | | |
| [redacted] | | | | | | | |

(b) (4)

See Part 5 for biocompatibility testing of all patient contacting materials.



28

Questions [redacted]

# PART 3
# DEVICE LABELING

**Introduction**

This section contains draft labeling, directions for use, and promotional material for the proposed automatic clip applier. Predicate directions for use labeling for the Hem-o-lok® reusable applier and clip system and U.S. Surgical Endoclip® automatic clip applier are provided to demonstrate substantial equivalence.

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

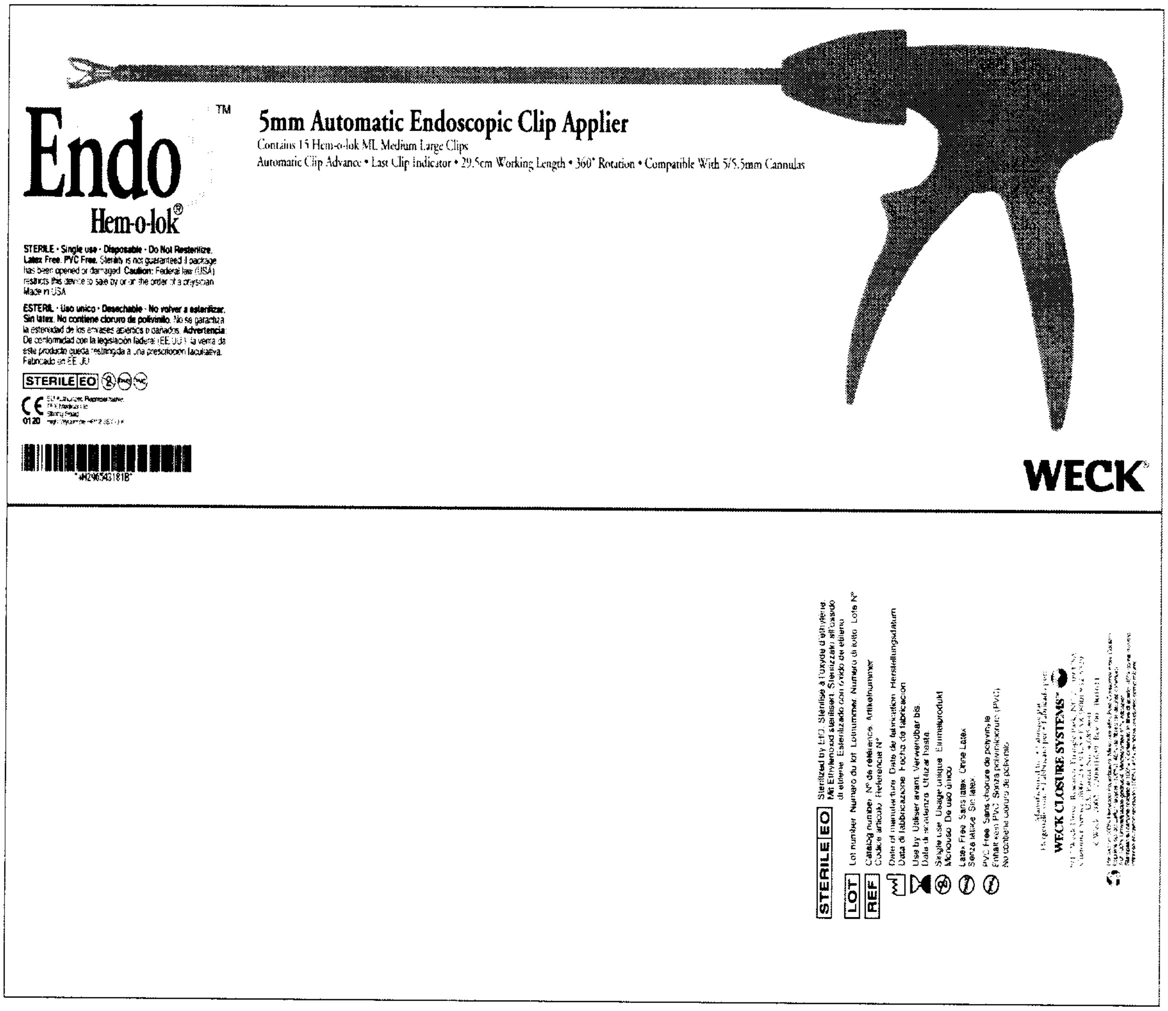
# PART 3
# DEVICE LABELING

**Proposed Automatic Ligating Clip Applier**
**Device Labeling**

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

# PART 3
# DEVICE LABELING




Box and sterile unit label

**PART 3**
**DEVICE LABELING**

## Representative Instructions for Use
**Medium Large Automatic Endoscopic Clip Applier**

**DESCRIPTION**
Weck Endo5 Hem-o-lok ML Medium Large automatic endoscopic ligating clip appliers are sterile, disposable devices containing 15 Hem-o-lok ML non-absorbable polymer ligating clips. These appliers automatically advance a new clip when the trigger is pulled back half-way to the handle. In addition, these appliers feature a shaft which rotates when the turn knob is rotated.

**INDICATIONS**
Weck Endo5 Hem-o-lok ML Medium Large automatic endoscopic ligating clip appliers are indicated for use as delivery devices for Hem-o-lok ML Medium Large non-absorbable polymer ligating clips. These appliers are designed for use with 5/5.5mm cannulas.

Hem-o-lok ligating clips are intended for use in procedures involving ligation of vessels or tissue structures. Surgeons should apply the appropriate size clip for the size of the vessel or tissue structure to be ligated such that the clip completely encompasses the vessel or tissue structure.

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

**CAUTION**
The clip must be latched to ensure proper ligation of the vessel or tissue. Inspect the ligation site after application to ensure proper closure. Weck recommends ligation of the renal artery with two (2) clips on the patient side in a nephrectomy. Application of a second clip on all other vessels should be dictated by the surgeon's judgement in all other cases.

The Hem-o-lok polymer ligating clip is not designed for use as a tissue marker. Weck recommends a 5mm Hem-o-lok endoscopic clip remover, Catalog #544121, be readily available during endoscopic surgery involving the use of Hem-o-lok clips.

Always check the alignment of the applier jaws before use. If this is not done, patient injury may occur. Always confirm that the clip remains in the applier jaws after insertion of the applier and clip through a cannula. Do not attempt to close the jaws on a vessel or anatomic structure without a clip properly loaded into the jaws. Closure of empty jaws on a vessel or anatomic structure is not recommended. Before applying a clip, verify the structural size and condition of the vessel or structure and use the proper clip size.
Ligating clip systems differ in closure characteristics according to clip design and other variables. It is the responsibility of the user to select structures for the application of clips and confirm clip security after placement, and after the use of other surgical devices in the immediate area of the application.
NOTE: Endo5 Hem-o-lok ML automatic endoscopic ligating clip appliers are sterile, single use and disposable. DO NOT resterilize.

# PART 3
# DEVICE LABELING

NOTE: The Hem-o-lok ML clip is a locking clip and is not recommended for use in intraoperative cholangiograms with bulbous (shouldered) tipped catheters. In the event of an unsuccessful ligation attempt, clear the applier jaws and apply a new clip.

**CARE AND HANDLING**

Applier jaws are delicate and can easily become damaged, as can some other applier components. Mishandling of appliers may result in improper load and/or closure of the ligating clip. Please examine the applier before surgery for potential damage. Pay particular attention to the jaws. Damaged or misaligned jaws may not allow clips to close acceptably for occlusion of intended structure.

**INSTRUCTIONS FOR USE**

The Hem-o-lok ML Medium Large clip is generally suited to vessels and tissue structures from 3 – 10mm in diameter. Surgeon judgement should dictate clip selection for specific applications.

Loading clips and inserting the applier down the cannula

1. The applier is supplied with the jaws empty. To load the applier, grasp the applier and pull the trigger half-way to the handle. A clip will advance into the jaws from the shaft. Loading a clip into the jaws may be performed before or after the applier shaft is advanced down a cannula.
2. Ensure the clip is positioned in the jaws as shown (illustration 1).
3. Compress the applier trigger and insert the applier jaws and shaft down the cannula. Maintain compression on the trigger until the jaws clear the cannula. NOTE: If no clip is in the jaws, it is not necessary to compress the applier trigger before inserting into the cannula.

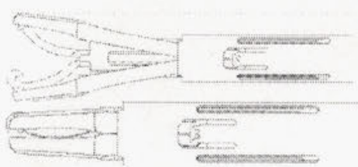
Clip positioning and closure

4. Sufficiently skeletonize the structure to be ligated to allow the locking mechanism of the clip to be clear of tissue. Do not use the clip or applier as a dissecting instrument.
5. During application, orient the single tooth of the ML clip as shown (illustration 1). This allows the user to visually confirm encapsulation of the structure being ligated. Position the clip around the tissue to be ligated in a manner that provides clear visualization of the locking mechanism (illustration 2). Apply sufficient force to the applier trigger so the jaws close and the clip locks shut (illustration 3). Releasing pressure on the trigger allows the applier to return to a reset position. When the applier is in the reset position, squeezing the trigger will automatically load the next clip into the jaws. NOTE: Always load clip into jaws prior to placing over vessel. Leave a distal cuff of tissue approximately 1-2mm from the ligating clip if the tissue is divided (illustration 4), i.e. do not use the side of the clip as a cutting guide.
6. A bright orange indicator entering the jaw will indicate that the applier is empty.

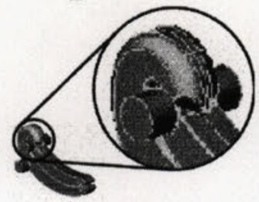
Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017



1

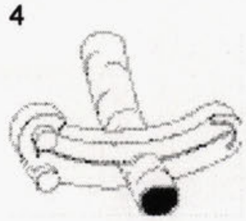


2



3

4



Withdrawal of the applier up the cannula
7. Withdraw the applier from the ligation site up through the cannula. NOTE: If a clip is visible in the jaws, it is necessary to compress the applier trigger before withdrawing the applier through the cannula.

**INSTRUCTIONS FOR INTRAOPERATIVE CHOLANGIOGRAM UTILIZING HEM-O-LOK ML CLIPS AND TAUT® LAPAROSCOPIC CHOLANGIOGRAM CATHETERS**
The Hem-o-lok ML clip is a locking clip and is only recommended for use in intraoperative cholangiograms with Taut, Inc., NON-bulbous (non-shouldered) tipped catheters, Catalog #s 18305 and 18400. Use of these catheters permit catheter removal without having to remove a locked Hem-o-lok ml clip. WARNING: Do not use the Hem-o-lok ML clip to secure any type of catheter other than the specific catalog numbers indicated above. Contact your local Weck representative for other catheter recommendations.

1. An optional Hem-o-lok ML clip (#1) is secured on the cystic duct to prevent egress of bile from the gallbladder ductotomy (illustration 5).
2. A Taut Intraoperative Cholangiogram Catheter catalog #18305 is placed through a standard ductotomy in the cystic duct and secured in place with a Hem-o-lok ML clip (#2) (illustration 5).
3. After completion of the cholangiogram, the Taut catheter is removed leaving the secure Hem-o-lok ML clip closed on the cystic duct (illustration 6).
4. A third Hem-o-lok ML clip (#3) is secured in place on the cystic duct (illustration 7).
5. The cystic duct is now divided using the security of the third clip for secure ligation (illustration 8).

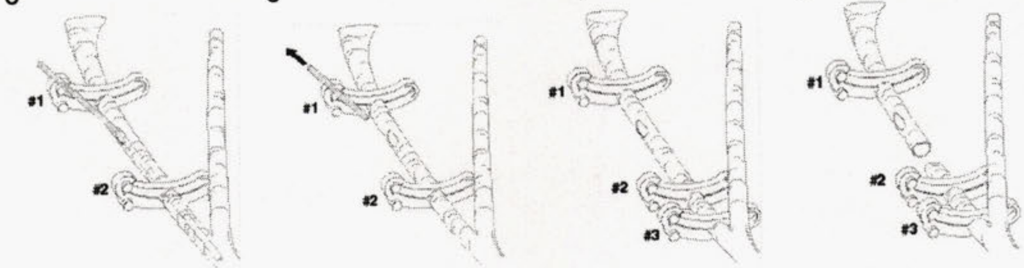


34

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



5 6 7 8




**Weck Closure Systems**

One Weck Drive
Research Triangle Park, NC 27709
(800) 234-Weck (919) 544-8000
FAX (800) 932-5329
Drawing No.
Revision No.
Component No.

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

# PART 3
# DEVICE LABELING

**Draft Hem-o-lok Automatic Promotional Claims**

Uses

Auto Open-L, catalog number 543181

Clinical Procedure: - The disposable Auto Open MLX applier will be a completely disposable, sterile unit with pre-loaded clips and is intended to be used for general use where a ligating clip is desired. These procedures include, but are not limited to the following: colon and rectal surgery, appendectomy, cholecystectomy, radical prostatectomy, nephrectomy, splenectomy and hysterectomy (TAH Mini-Laperotomy).

Endo5 Automatic, catalog number 543965

The disposable automatic endoscopic applier will be completely disposable, sterile unit with pre-loaded clips and is intended to be used for general laparoscopic use where a ligating clip is desired. These procedures include, but are not limited to the following procedures; laparoscopic cholecystectomy, laparoscopic nephrectomy, laparoscopic appendectomy, laparoscopic hysterectomy, and laparoscopic splenectomy.

Advertising Claims

- Atraumatic jaws will not damage vessels if closed without a clip.
- A highly visible indicator in the applier jaw signals complete use of clips and prevents jaw closure.
- The Hem-o-lok clip provides the convenience and speed of ligating clips with the security of suture.
- The Hem-o-lok clip locks through a wide range of tissue to ligate vessels. This speeds ligation through the application process by minimizing tissue dissection.
- The Hem-o-lok clip has polymer teeth to enhance the security of the clip.
- The Hem-o-lok clip has received very high ratings in a number of different open and laparoscopic surgical procedures, including colon/rectal-resection, nephrectomy, prostatectomy, lobectomy, appendectomy, gastrectomy, hysterectomy, cholecystesctomy and saphenous vein ligation.
- The Hem-o-lok clips which are a non-absorbable polymer, in contrast to absorbable polymer clips, will not harbor or promote infection in an infected field.
- The Hem-o-lok clip facilitates minimally-invasive surgery by providing clip compression down a cannula and wide opening within the cavity for encompassment of tissue. The firm resistance of the Hem-o-lok clip to slide-back in the applier also facilitates its ability to engulf tissue because it allows the clip to abut tissue firmly before closure in the applier.

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

# PART 3
# DEVICE LABELING

Promotional Claims (cont'd)

- The Hem-o-lok "living-hinge" virtually eliminates dropped clips in the operative field which is common to metal clips passing through small cannulas or using in tight or small operative fields. This saves procedure time, the need for additional clips reducing overall costs of the procedure.
- The tactile feedback of the locking clip facilitates a quick closure process because it tells the surgeon that the clip is closed properly - well aligned and not overclosed or underclosed - uniformly closed each time. Non-absorbable composition of the clip lends itself to a slim clip construction. This speeds ligation over other methods of ligature.
- The Hem-o-lok clip ligates all vessels and tissue bundles within the specified range.
- Polyacetal has been previously used in surgical implants such as heart valves and hip prosthesis.
- Non-absorbable polyacetal does not break down in vivo, and therefore does not develop the fissures that have been found in studies on absorbable clips to harbor bacteria.
- Hem-o-lok ligating clips are radiotransparent and do not cause artifacts on CAT scanning or MRI.
- The Hem-o-lok clips do not scissor when placed on vessels and tissue bundles.
- Superb financial outcomes as demonstrated on the financial analysis worksheet when comparing manual versus automatic clip appliers.
- The Hem-o-lok clip bosses eliminates clip push-back in applier jaws, even when forced onto vessels.
- The Hem-o-lok ML clip, when used with an Endo5, clip applier eliminates the need for larger port/cannulas for ligation.
- The Hem-o-lok Large clip is as secure as 2-0 silk suture ligature. In an in-vitro bench test, The Hem-o-lok clip was equal to that of the 2-0 silk suture ligature over a range of 100mm Hg to 1000mm Hg. A pressure of 1000mm Hg is approximately 5 times that is sustainable with human life.
- Latex free and PVC free.
- To allow temporary clip placement, a Hem-o-lok clip remover is available for all clip sizes.
- Unlike any other metal clip, the Hem-o-lok Ligation Clip is often referred to as "A "Suture less Tie" with unprecedented security.

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

# PART 3
# DEVICE LABELING

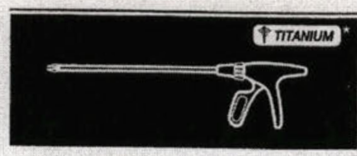
**Predicate Device Labeling (Directions for Use)**

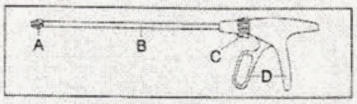
Questions Contact FDA/CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

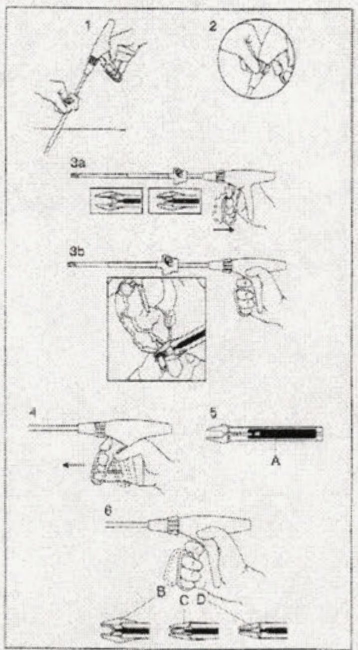
Records Processed under FOI request 2017-6482; Released by CDRH on 10/03/2017

# PART 3
# DEVICE LABELING

Auto Suture*
**ENDO CLIP* II ML**
DISPOSABLE CLIP APPLIER




Auto Suture*
**ENDO CLIP* II ML**
DISPOSABLE CLIP APPLIER

ENGLISH

**BEFORE USING PRODUCT,**
**READ THE FOLLOWING INFORMATION THOROUGHLY.**

**IMPORTANT!**
This booklet is designed to assist in using the Auto Suture* ENDO CLIP* II ML clip applier. It is not a reference to surgical endoscopic techniques. For information on endoscopic techniques, complications, and hazards, please see the books: *Surgical Laparoscopy Update*, Karl A. Zucker, Ed., Quality Medical Publishing, Inc., St. Louis, MO 1993 and *Endoscopic Surgery*, R.A. White, S.R. Klein, Mosby-Year Book, Inc., St. Louis, MO 1991.

**CAUTION:** Federal (USA) law restricts this device to sale, and use by, or on the order of, a physician.

**INDICATIONS**
The Auto Suture* ENDO CLIP* II ML 10 mm clip applier has application in many types of endoscopic procedures to achieve occlusion of vessels and other tubular structures and for radiographic markings.

**EFFECTS**
The Auto Suture* ENDO CLIP* II ML clip applier contains 20 titanium clips. The appliers are designed for introduction and use through all appropriately sized Auto Suture* trocar sleeves, or larger sized trocar sleeves with the use of an appropriate converter.

**SCHEMATIC VIEW AND NOMENCLATURE**
A) JAW
B) SHAFT
C) ROTATION COLLAR
D) HANDLE

**INSTRUCTIONS FOR USE**
1. Introduce the ENDO CLIP* II ML clip applier through the appropriately sized Auto Suture* trocar sleeve, or larger sized trocar sleeve with the use of a converter, **PRIOR** to loading a clip into the jaw.

**If the shaft is introduced via the trocar sleeve with a clip in its jaw, the open clip may dislodge and fall into the body cavity.**

2. The shaft rotates 360° in either direction. Adjust the instrument jaw for maximum visibility by rotating the grooved rotation collar in either direction.

**The applier can be fired in two (2) ways:**
3a. Before placing the instrument jaw around the structure to be occluded, squeeze the handle until an audible click is heard to feed a clip into the jaw. Place the instrument jaw around the structure to be occluded, making certain that the tissue fits completely within the confines of the jaw. Complete the handle squeeze to close the clip on the tissue.

3b. Place the jaw around the tissue and then completely squeeze the handle to both load and close the clip in one continuous squeezing motion.

**Visually confirm that the clip is positioned within the jaw and is free of other clips or obstructions before squeezing the handle to close the clip.**

Regardless of whether the applier is fired as in 3a or 3b above, its application across another clip or obstruction may result in malformation of the clip which may result in leakage or damage to the instrument jaw. Squeeze the handle firmly as far as it will go.
As the handle is squeezed, the clip is held firmly by the jaw and closed around the tissue.

**FAILURE TO SQUEEZE THE HANDLE AS FAR AS IT WILL GO CAN RESULT IN CLIP MALFORMATION AND POSSIBLE BLEEDING OR LEAKAGE.**

4. Release the handle to disengage the clip and remove the applier from the vessel or structure. To advance the new clip for successive application, squeeze the handle in the same manner as illustrated in step 3a or 3b.

**NOTE: Inspect all clips which have been placed, confirming establishment of hemostasis or occlusion without leakage.**

5. When there are no clips left in the applier, a bright yellow bar will automatically appear in the clip window, indicating that it is empty of clips. A safety interlock feature prevents the handle from being squeezed and consequently, the empty jaw will not close on the tissue.

**THE JAW MUST NOT CONTAIN AN OPEN CLIP WHEN THE SHAFT IS REMOVED FROM THE TROCAR SLEEVE.**
If the applier is removed from the trocar sleeve with an open clip in the jaw, the clip could dislodge and fall into the body cavity. In the event an unapplied clip is in the jaw, squeeze the handle and remove the instrument from the trocar sleeve with the jaw in the closed position.

A) YELLOW BAR

6. If desired, the ENDO CLIP* II ML clip applier may be used to secure a catheter for cholangiography. In squeezing the handle, a distinct point is reached where there is an audible click indicating that the clip is in the "cholangio-zone." The clip remains on the cystic duct and is released from the jaw by releasing pressure on the handle in the "cholangio-zone." Once the ENDO CLIP* II ML clip applier is removed from the cystic duct, ensure that there is no tissue present in the jaw. Complete the handle squeeze to prepare the instrument for the next application.

**SEQUENCE OF CLOSURE**
B) OPEN
C) "CHOLANGIO-ZONE"
D) CLOSED

Auto Suture*
**ENDO CLIP* II ML**
POSE-CLIPS ENDO CLIP* II ML

FRANÇAIS

**AVANT D'UTILISER CET INSTRUMENT,**
**LIRE ATTENTIVEMENT LES INFORMATIONS SUIVANTES.**

**ATTENTION**
La présente notice a été rédigée afin de vous assister lors de vos utilisatio[illegible] ENDO CLIP* II ML Auto Suture* à usage unique. Il ne s'agit pas d'un docu[illegible] pour les techniques de la laparoscopie chirurgicale. Pour les informations [illegible] les complications et les risques, liés à l'endoscopie, veuillez vous référer [illegible] *Surgical Laparoscopy Update* (Karl A. Zucker, Ed., Quality Medical Publi[illegible] Louis, MO, 1993) et *Endoscopic Surgery* (R.A. White, S.R. Klein, Mosby [illegible] Louis, MO, 1991).

**INDICATIONS**
Le Pose-Clips ENDO CLIP* II ML 10 mm Auto Suture* s'utilise au cours [illegible] interventions par voie laparoscopique pour assurer la ligature de vaisseau[illegible] structures tubulaires et en repérages radiographiques.

**EFFETS**
Le Pose-Clips ENDO CLIP* II ML Auto Suture* contient 20 clips Titane. C[illegible] conçu pour être introduit et utilisé à travers toutes gaines de trocart Auto S[illegible] approprié, ou des gaines plus larges à condition que celles-ci soient munie[illegible] convient.

**VUE SCHEMATIQUE ET DESIGNATION DES PIECES**
A) MACHOIRES
B) AXE
C) COLLIER ROTATIF
D) POIGNEE

**MODE D'EMPLOI**
1. Introduire le pose-clips ENDO CLIP* ML dans la gaine de trocart Auto S[illegible] approprié ou une gaine plus large, à condition que celle-ci soit munie d'u[illegible] tout chargement de clip dans les machoires.

**Si on inserait l'axe machoires munies d'un clip, à travers la [illegible] trocart, ce clip ouvert pourrait se déloger et tomber dans la [illegible] corporelle.**

2. L'axe est rotatif sur 360°, dans un sens comme dans l'autre. On règle le[illegible] l'instrument par rotation dans un sens ou dans l'autre du collier rotatif, de [illegible] procurer une visibilité maximale.

**Il existe deux (2) manières d'actionner:**
3a. Avant tout positionnement des machoires autour de la structure à ligat[illegible] la poignée afin de faire passer un clip dans les machoires, ce qui est confir[illegible] On amène les machoires autour de la structure à ligaturer en s'assurant qu[illegible] complètement intégrés entre les limites des machoires. On ferme la poigné[illegible] fermer le clip dans les tissus.

3b. On positionne les machoires autour des tissus et on ferme à fond la poi[illegible] en un seul geste continu de charger et de fermer le clip.

**On vérifie visuellement que le clip se trouve à l'intérieur des ma[illegible] ci étant libre de tous autres clips ou d'autres obstructions, avant [illegible] poignée pour fermer le clip.**

Que l'on actionne l'instrument selon le principe 3a ou 3b indiqués plus hau[illegible] par-dessus un autre clip ou toute autre obstruction pourrait entraîner une [illegible] de clip, ce qui pourrait avoir pour effet des écoulements ou la détérioration [illegible] l'instrument. On appuie fermement et à fond sur la poignée. Pendant ce tem[illegible] solidement retenu dans la machoire en se fermant autour des tissus.

**LE FAIT DE NE PAS APPUYER A FOND SUR LA POIGNEE POURR[illegible] UNE MAUVAISE FORMATION DE CLIPS, CE QUI POURRAIT AVOI[illegible] DES SAIGNEMENTS OU DES ECOULEMENTS.**

4. On relâche la poignée afin de dégager le clip tout en dégageant le pose-c[illegible] ou de la structure. En poses successives, et pour faire avancer le clip suiva[illegible] la manière indiquée en 3a ou 3b.

**N.B. Vérifier que chaque pose de clip est bien suivie d'hémosta[illegible] ligature sans écoulement.**

5. Lorsqu'il ne reste plus aucun clip dans l'instrument, une bande jaune vi[illegible] automatiquement dans l'indicateur. Une sécurité interlock empêche toute p[illegible] poignée, ce qui signifie que la machoire vide ne peut se refermer autour de[illegible]

**LES MACHOIRES NE DOIVENT PAS CONTENIR DE CLIP OUVERT [illegible] DU RETRAIT DE L'AXE DE LA GAINE DU TROCART.**

Si on retire l'axe, dont les machoires renferment un clip ouvert, de la gaine [illegible] pourrait se déloger et tomber dans la cavité corporelle. Au cas où un clip [illegible] dans les machoires, on appuie sur la poignée et on retire l'instrument, mach[illegible] la gaine de trocart.

A) BANDE JAUNE

6. On peut, si on le souhaite, utiliser le pose-clips ENDO CLIP* II ML en [illegible] pour fixer le cathéter. Au cours de la pression sur la poignée, un déclic se f[illegible] indiquer que le clip se trouve en "zone cholangio". Le clip reste donc sur le [illegible] dégageant des machoires, dans cette "zone cholangio", dès que l'on relâche [illegible] poignée. Une fois l'applicateur ENDO CLIP* ML retiré du canal cystique, on [illegible] absence de tissus dans les machoires et on complète la fermeture de la poig[illegible] prépare l'instrument à la pose suivante.

**LES ETAPES DE LA FERMETURE**
B) OUVERT
C) "ZONE CHOLANGIO"
D) FERMÉ

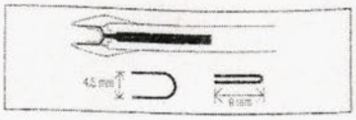
USSC

10000-02131



39

# PART 3
# DEVICE LABELING




The Auto Suture* ENDO CLIP* II ML clip applier contains 20 medium-large clips of rectangular titanium wire. The clip span is approximately 4.5 mm before closure and is approximately 9 mm long when closed. The shape of the closed clip may vary according to tissue thickness. The overall length of the shaft is approximately 29 cm (11.5") and is designed for introduction and use through all appropriately sized Auto Suture* trocar sleeves or larger sized trocar sleeves with the use of a converter.

APPROXIMATE CLIP SIZE SHOWN

**CAUTIONS**

1. Prior to insertion or removal of the ENDO CLIP* II ML clip applier through the appropriately sized Auto Suture* trocar sleeve, or larger sized trocar sleeve with the use of a converter, ensure that a clip is not preloaded into the jaw. Failure to do so can result in an open clip being dropped into the body cavity.

2. Prior to squeezing the handle to place a clip, visually confirm that the clip is positioned free of other clips and obstructions. Firing a clip over a clip may result in malformed clips, which may cause lack of hemostasis or damage to the instrument jaw.

3. Make certain the tissue to be occluded fits completely within the confines of the clip or bleeding and/or leakage may result.

4. **WHEN FIRING THE INSTRUMENT, SQUEEZE THE HANDLE FIRMLY AS FAR AS IT WILL GO.** Failure to squeeze the handle completely can result in clip malformation and possible bleeding and/or leakage.

5. Inspect all clips which have been placed to confirm that none have been applied across other clips or obstructions and that hemostasis or occlusion without leakage has been established. If minor bleeding and/or leakage is observed after successive applications, electrocautery may be necessary to complete the occlusion.

6. When transecting the occluded structure, leave a sufficient margin of tissue to reduce the potential for dislodgement of the nearest clip. Dislodgement of a clip may result in bleeding and/or leakage.

7. After all clips in the ENDO CLIP* II ML clip applier have been fired, a bright yellow bar will automatically appear in the clip window to alert the surgeon that the cartridge is empty. At this point, the handle can no longer be squeezed.

8. Endoscopic procedures should be performed only by physicians having adequate training and familiarity with endoscopic techniques. Consult the medical literature relative to techniques, complications and hazards, prior to the performance of any endoscopic procedure.

9. A thorough understanding of the principles and techniques involved in endoscopic laser and electrosurgical procedures is necessary to avoid shock and burn hazards to both patient and operator(s) or damage to the instrument. Verify compatibility of instrumentation and ensure that electrical isolation or grounding is not compromised.

10. Caution should be exercised when utilizing electrosurgical techniques such as electrocautery or electrocoagulation in the vicinity of any metallic clip. Inadvertent contact with a metallic clip by the energized electrosurgical device may cause unintentional cauterization or electrocoagulation at or around the clip site which may cause necrosis of the affected tissue. Dislodgement of the clip may occur, resulting in loss of hemostasis or leakage.

11. Some surgeons believe that titanium clips should not be used in the brain.

12. This device is provided STERILE and is intended for use in a SINGLE procedure only. DISCARD AFTER USE. DO NOT RESTERILIZE.

**CONTRAINDICATIONS**

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

2. Do not use the ENDO CLIP* II ML clip applier on the renal artery, iliac artery, or other vessels upon which metal ligating clips would not normally be used.

Le Pose-Clips ENDO CLIP* ML Auto Suture* contient 20 clips Titane … rectangulaires. L'écartement des jambes du clip est de l'ordre de 4,5 m… longueur du clip étant d'environ 9 mm après fermeture. La forme du clip … selon l'épaisseur des tissus. La longueur hors tout de l'axe est d'environ … étant conçu pour être inséré à travers une gaine de trocart Auto Suture* … ou une gaine de diamètre plus large munie d'un réducteur.

CLIP GRANDEUR APPROXIMATIVE

**PRECAUTIONS**

1. Avant tout introduction ou tout retrait du pose-clips ENDO CLIP* II … trocart Auto Suture* de diamètre approprié, ou une gaine plus large mu… vérifier qu'aucun clip n'est préchargé dans les mâchoires, faute de quoi … tomber le clip ouvert dans la cavité corporelle.

2. Avant toute pression sur la poignée, bien vérifier aussi absence d'aut… obstructions dans les mâchoires. Le fait de poser un clip par-dessus un … entraîner une mauvaise fermeture de clip, ce qui pourrait être à l'origine … d'hémostase ou de détériorations des mâchoires.

3. S'assurer que les tissus à ligaturer sont complètement intégrés dans … faute de quoi il pourrait survenir des saignements et/ou des écoulements.

4. **LORS DES POSES DE CLIPS, IL CONVIENT D'APPUYER … POIGNÉE**, faute de quoi les clips pourraient mal se fermer, ce qui pou… saignements et/ou des écoulements.

5. Vérifier chaque pose de clip pour être certain qu'aucun n'est posé su… d'autres obstructions et que la pose est bien suivie d'hémostase et de l'… écoulement. S'il se produit des saignements ou écoulements peu impor… poses successives, on peut avoir recours à l'électrocoagulation afin de …

6. Lors de la transection d'une structure ligaturée, laisser une marge tis… minimiser les risques de déplacement du clip le plus proche. Tout délo… entraîner des saignements ou des écoulements.

7. A la suite de la pose de tous les clips du pose-clips ENDO CLIP* II M… vif apparaît automatiquement dans l'indicateur afin de prévenir le chirur… est vide. Dès ce même moment, il ne peut plus appuyer sur la poignée.

8. Seuls les chirurgiens ayant bénéficié d'une formation et d'une expéri… doivent réaliser les interventions par voie laparoscopique. Avant toute … il y a lieu de consulter les documentations médicales se rapportant aux … complications et aux risques inhérents.

9. Une connaissance approfondie des principes et techniques des inter… laparoscopiques faisant appel au laser et à l'électrochirurgie est indisp… risques de commotion et de brûlure à la fois pour les patients et pour le… chirurgiens. Il y a lieu de vérifier la compatibilité des instrumentations … l'isolation électrique ou la mise à la masse sont indispensables.

10. Il convient de prendre le plus grand soin en ayant recours aux techn… électrochirurgicales telle que coagulation, par exemple à un site peu éloi… métallique. Si un clip métallique entre fortuitement en contact avec un … électrochirurgical traversé par le courant, on peut observer une électroc… inattendue au site du clip ou près de celui-ci et des nécroses tissulaires … ainsi affectés. Le clip pourrait en outre en être délogé, ce qui pourrait au… perte d'hémostase ou des écoulements.

11. Certains chirurgiens pensent que les clips Titane ne doivent pas … cerveau.

12. Cet instrument n'est pas conçu pour être utilisé à d'autres fins que c… JETER APRÈS EMPLOI. NE PAS RESTÉRILISER.

**CONTRE-INDICATIONS**

1. Cet instrument n'est pas conçu pour la ligature contraceptive des tro… l'utiliser pour procurer l'hémostase à la suite de la transection de la tro…

2. Ne pas utiliser l'applicateur ENDO CLIP* II ML à usage unique en pré… rénale, de l'artère iliaque ou d'autres vaisseaux où l'on n'a pas normalem… clips métalliques occlusifs.

製造番号

LOT ロットナンバー

EXP 使用期限

STERILE 滅菌

再使用不可

CE 0123

DO NOT EXPOSE TO TEMPERATURES ABOVE 130° F (54° C).

NE PAS EXPOSER A DES TEMPERATURES SUPE…

Auto Suture European Services Center, S.A., 78990 Elancourt, France.

輸入販売元　オートスーチャージャパン株式会社

*Trademark of United States Surgical Corporation.

Manufactured by: United States Surgical Corporation, Norwalk, Connecticut 06856

©1999 United States Surgical Corporation 4/99 All Rights Reserved. Made in the U.S.A. 01

*Marque de United States Surgical Corporation

Fabriqué par: United States Surgical Corporation, Norwalk, Connectic…

Tous droits réservés. Fabriqué aux États-Unis

40

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

# PART 3
# DEVICE LABELING

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

## WECK Hem-o-lok®

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

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

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

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

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

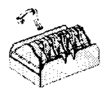
**Charakteristischen der Anlegezange:** Kann zu Reinigungs- und Sterilisationszwecken vollständig geöffnet werden • Zueinandergehörige Clip-Magazine und Clipanlegezangen sind mit einem Farbencode versehen, der die Identifizierung erleichtert.

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

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

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

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



CE 0120

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

CE

STERILE EO

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

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

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

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

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

WECK CLOSURE SYSTEMS™

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

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

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

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

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

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

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

WECK CLOSURE SYSTEMS™

Manufactured by: • Fabriqué par: • Hergestellt von: • Fabbricato per • Fabricado por:
Weck Closure Systems, One Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 800 234-WECK, 919 544-8000 • Fax: 800 932-5329
©Weck Closure Systems, 2001 220001054 Rev. 00 L03156

Printed on recycled paper. Minimum 25% post-consumer fiber and 25% pre-consumer recovered material. Acid free. • Imprimé sur du papier recyclé. 25% de fibres de déchet et 25% de matière recyclée minimum. Sans acide. • Auf Umweltpapier säurefrei gedruckt. Mindestanteil 25% Altpapier und 25% Recyclingmaterial. Säurefrei. • Stampato su carta riciclata. Come minimo, 25% di fibre di scarto e 25% di materiali di recupero riciclati. Senza acidi. • Impreso en papel reciclado. 25% de fibras residuales y 25% de materia reciclada como minimo. Sin ácido.

41

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

# PART 3
# DEVICE LABELING

## INDICATIONS

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

Hem-o-lok ligating clips are intended for use in procedures involving ligation of vessels or tissue structures. Surgeons should apply the appropriate size clip for the size of the vessel or tissue structure to be ligated such that the clip completely encompasses the vessel or tissue structure.

## CONTRAINDICATIONS

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

## PRECAUTION

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

## CAUTION

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

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

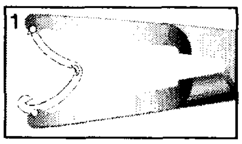
## CARE, CLEANING, AND STERILIZATION

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

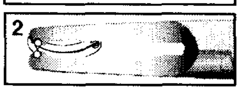
**All Weck Closure Systems ring-handled manual load reusable ligating clip appliers are supplied nonsterile. The instrument should be cleaned and sterilized prior to each use. Clean the instrument before sterilization and in the same manner as any reusable instrument and in accordance with hospital practice.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

## INSTRUCTIONS FOR USE

1. To load the applier, grasp the applier and carefully insert the jaws of the applier into the cartridge slot, making sure the jaws are perpendicular to the base of the cartridge. Gently press the applier over the clip until there is an audible click. Do not force the applier into the cartridge or onto the clip. The applier should enter and withdraw from the cartridge easily.



2. Remove the applier from the cartridge ensuring the clip is held securely in the applier jaws **(illustration 1)**. It may be necessary to hold the cartridge to allow the clip to be removed.



3. Position the clip around the tissue to be ligated. Apply sufficient force to the applier handles so the jaws close and the clip locks shut **(illustration 2)**. Releasing pressure on the applier handles allows the applier to return to a fully open position. Withdraw the applier from the ligation site.

## LIGATING SYSTEM COMPATIBILITY

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



42

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

# PART 4
# STATEMENT OF SUBSTANTIAL EQUIVALENCE

## 1. SUMMARY OF SIMILARITIES AND DIFFERENCES

The clips delivered by the proposed automatic applier described in this submission are substantially equivalent in design, materials, manufacturing and intended use to Weck Hem-o-lok clips which received marketing clearance under: **K902108** (Original submission, medium size clips); **K922186** (addition of small and large size clips); **K941972** (change in ownership); **K982941 and K982944** (change in materials and labeling); **K993157** (change to indications and contraindications); and **K003337** (promotion for specific operating procedures).

The original Hem-o-lok clip was insignificantly modified to accommodate automatic application. A radius was added to the clip profile to reduce the force required to lock the clip during closure, and the boss height in the endoscopic model was reduced by .0025" to enable delivery down a 5 mm cannula. The non-affect of these changes on safety and effectiveness was confirmed in test data provided in **Part 5**.

The delivery mechanism of the proposed automatic applier is substantially equivalent to the following legally marketed predicate devices: **K883018** (U.S.S.C. AutoSuture Endoclip 5mm Disposable Clip Applier); and **21CFR §878.4800** (Weck reusable ligating clip appliers). The proposed automatic applier and the predicate devices:

- Have the same intended use, to effectuate hemostasis by vessel ligation;
- Have the same primary mechanical functions: clip feeding, approximation (positioning the clip around the vessel), and closure;

With respect to the automatic predicate, both devices:

- include multiple ligating clips which are supplied as an integral part of the device;
- Employ similar handle, shaft and jaw configurations; and
- Are supplied sterile for single use only.

For substantial equivalence purposes, **Table 2** compares similarities and differences of the proposed automatic applier to the predicate clip systems. Minor differences between the devices are not considered significant technological differences and do not affect safety or effectiveness of the subject device.



43

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

# PART 4
# STATEMENT OF SUBSTANTIAL EQUIVALENCE

## 2. SUBSTANTIAL EQUIVALENCE DECISION TREE

The 510(k) "Substantial Equivalence" Decision-Making Process (Detailed) as outlined in ODE Guidance Document #K86-3, Guidance on the CDRH Premarket Notification Review Program, was used to determine substantial equivalence. The answers to the following questions lead to a determination of substantial equivalence.

a) **Does new device have same indication statements?**

**Yes.** Indication statements for the proposed automatic applier are the same as those of the predicate device. All are indicated for ligation of vessels and tissue structures.

b) **Does new device have same technological characteristics, e.g. design, materials, etc.?**

**Yes.** The clip employed in the proposed automatic applier is an insignificantly modified version of the single application Hem-o-lok clip. The delivery device design is similar to the predicate Autosuture device. A comparison of the proposed and predicate devices in **Table 2** shows that the proposed automatic clip applier has the same basic technological features as the predicate devices.

c) **Are descriptive characteristics precise enough to ensure equivalence?**

**No.** The differences noted from the comparison of the proposed and predicate devices in **Table 2** show only minor differences between the proposed and predicate devices. Performance and biocompatibility testing has been conducted on the proposed automatic applier to demonstrate that these minor differences raise no new questions of safety and effectiveness.

d) **Are performance data available to assess equivalence?**

**Yes.** Biocompatibility testing demonstrates the acceptability of the materials used in the proposed automatic applier. Bench and animal testing was initiated to assess performance. The results of testing are included in **Part 5**.


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



e) **Performance data demonstrate equivalence?**

**Yes**. Product testing included in **Part 5** includes biocompatibility, bench and animal testing. Results demonstrate that the proposed device performs equivalently to the predicate devices. Biocompatibility test data demonstrate that the materials with patient contact are non-toxic.

## 3. SUMMARY OF SUBSTANTIAL EQUIVALENCE STATEMENT

The following points summarize the statement of substantial equivalence for the proposed automatic applier.

- The intended use and principle of operation of the proposed automatic clip applier are equivalent to those of predicate devices.
- The proposed device has the same technological characteristics as the predicate devices.
- The proposed automatic clip applier is functionally equivalent to the predicate devices, i.e., differences between the proposed device and predicates do not adversely affect performance and safety.

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

# PART 4
## STATEMENT OF SUBSTANTIAL EQUIVALENCE

**Table 2. Differences and Similarities Between the Proposed Automatic Applier and the Predicate Clip Systems**

| Characteristic | Proposed Automatic Clip Applier | Predicate Hem-o-lok Clip | AutoSuture EndoClip Automatic Clip Applier |
|---|---|---|---|
| Indications for use | Weck Hem-o-lok Automatic Ligating Clip Appliers are indicated for use as delivery devices for Hem-o-lok non-absorbable polymer ligating clips. Hem-o-lok ligating clips are intended for use in procedures involving ligation of vessels or tissue structures. Surgeons should apply the appropriate size clip for the size of the vessel or tissue structures to be ligated such that the clip completely encompasses the vessel or tissue structure. | Hem-o-lok ligating clips are intended for use in procedures involving ligation of vessels or tissue structures. Surgeons should apply the appropriate size clip for the size of the vessel or tissue structures to be ligated such that the clip completely encompasses the vessel or tissue structure. | The Auto Suture ENDO CLIP clip applier has application in many types of endoscopic procedures to achieve occlusion of vessels and other small tissue structures, and for radiographic markings. |
| How supplied | Sterile, single use package. | Sterile, single use clips. Reusable applier. | Sterile, single use package. |
| Delivery system | The delivery system consists of handle, shaft containing multiple clips, and jaw. The open model has a ring handled grip whereas the endo is a pistol grip. A new clip will automatically be delivered into the jaw during the firing stroke. | Stainless steel reusable endo and open surgery appliers are supplied separate from the disposable clips. Each locking polymer clip must be manually loaded from a 6-clip cartridge prior to application. | The delivery system consists of a hand-held, pistol-grip style device with a 5mm diameter shaft containing multiple unformed titanium clips, and jaw. A new clip will automatically be delivered into the jaw during the firing stroke. |
| Sterilization | Ethylene Oxide Gas | Ethylene Oxide Gas | Ethylene Oxide Gas |
| Clip Design / Geometry | Locking non-absorbable Medium-large and Large polymer clip. | Locking non-absorbable Medium, Medium-large, and Large polymer clip. | Medium-large titanium clip of rectangular cross-section wire |
| Clip counter | Colored (orange) indicator enters jaw after last clip is used and locks the jaw to prevent jaw closure. | NA – manual system single clip application system | Colored (red) indicator bar appears at rear of handle after last clip is fired. Handle is locked after last clip is fired. |
| Firing Sequence | Two-stage, Clip enters jaw in a semi-closed orientation and then opens fully with anti-backup during first stage of firing stroke. Clip closes and latches on second stage of firing stroke. Clip can be reopened and moved to alternate location prior to latching during second stage. | NA – manual system | Two-stage, Clip enters jaw with anti-backup during first stage of firing stroke. Clip closes (forma) on second stage of firing stroke, anti-backup continues through beginning of second stage only to allow for partial closure. |
| Number of Clips | 15 | 6 per cartridge | 20 |



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

46

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

# PART 5
# PRODUCT TESTING

**Introduction**

Testing presented in this part includes reliability, biocompatibility and animal tests conducted on the proposed automatic clip applier. All testing was conducted on sterilized representative product.

The endoscopic model was used for all testing except for biocompatibility testing, which additionally used the open surgery applier. Where applicable, data on devices provides a basis for comparison for demonstrating substantial equivalence of the performance and safety of the proposed automatic clip applier.

## RELIABILITY TESTING

(b) (4)

[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



**Conclusion:**
The results demonstrate that the proposed device maintains a leak rate similar to the predicate devices. The results show the proposed automatic applier is considered to be substantially equivalent to the predicate devices in terms of maximum leak rate.

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

Page 42 redacted for the following reason:
- - - - - - - - - - - - - - - - - - - - -
(b)(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



**Results:**

(b) (4)

[redacted]

**Conclusions:**

The results demonstrate that the proposed automatic appliers perform at a reliability of 0.95 at a 95% confidence level. Therefore, in terms of reliability performance under overstress conditions, the proposed automatic applier is considered to be substantially equivalent.

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

Page 44 redacted for the following reason:
- - - - - - - - - - - - - - - - - - - - -
(b)(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



**4. CONCLUSION**

It was demonstrated that all materials with direct patient contact passed all tests recommended in the ISO 10993-1 guidance. All materials with indirect contact were shown to be non-toxic based on cytotoxicity testing.

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

# PART 5
# PRODUCT TESTING

(b) (4)

[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

**PART 5**
## PRODUCT TESTING

(b) (4)

[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)

[redacted]

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

(b) (4)

[redacted]

5.0 **CONCLUSION:**

These tests conclude that th(b) (4) [redacted] acceptable for prolonged and permanent contact applications.

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

# PART 5

(b) (4)

[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)

[redacted]

**CONCLUSION: THE TEST ARTICLE PASSES THE TEST.**

Approval: ______________________ Date: ______________
Jason Klabon, MS

(b) (4)

[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

## PART 5

(b) (4)

[redacted]

59

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

# PART 5
## PRODUCT TESTING

(b) (4)

[redacted]

(b) (4)

[redacted]



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

60

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

(b) (4)

[redacted]



61

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

# PART 5
# PRODUCT TESTING

## ANIMAL TESTING

(b) (4)

[redacted]



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

62

Pages 56 through 58 redacted for the following reasons:
- - - - - - - - - - - - - - - - - - - - - - - - - - - -
(b)(4)

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



## DISCUSSION / CONCLUSIONS

(b) (4)
[redacted]

**CONCLUSION:**
The proposed Hem-o-lok ML Endo 5 Automatic Applier is substantially equivalent to the predicate devices in the application of ligating targeted structures throughout the range of tests included in the study. (b) (4) [redacted] (b) (4) [redacted] (b) (4) [redacted] e device can be shown to be substantially equivalent and fit for its intended purpose.



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

66

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

# PART 6
## PACKAGING AND STERILIZATION

(b) (4)

[redacted]



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

67

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

**PART 7**
**INDICATION FOR USE**

# Statement of Indications For Use

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

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

Weck Hem-o-lok Automatic Ligating Clip Appliers are indicated for use as delivery devices for Hem-o-lok non-absorbable polymer ligating clips. Hem-o-lok ligating clips are intended for use in procedures involving ligation of vessels or tissue structures. Surgeons should apply the appropriate size clip for the size of the vessel or tissue structures to be ligated such that the clip completely encompasses the vessel or tissue structure.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

| | | |
|---|---|---|
| Prescription Use<br>(Per 21 CRF 801.109) | OR | Over-The-Counter Use<br>(Optional Format 1-2-96) |



68

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

## PART 8
## TRUTHFUL AND ACCURACY STATEMENT

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT

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

James L. Lucky, V.P., RA/QA

5/31/02
Date

(510(k) number)


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

# PART 9
# SUMMARY OF SAFETY AND EFFECTIVENESS

## 510(k) SUMMARY

Pursuant to §513(i)(3)(A) of the Food, Drug, and cosmetic Act, Weck submits this summary of safety and effectiveness.

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

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

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

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

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

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

4. **Description of the Device**

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

5. **Intended Use of the Device**

Weck Hem-o-lok Automatic Ligating Clip Appliers are indicated for use as delivery devices for Hem-o-lok non-absorbable polymer ligating clips. Hem-o-lok ligating clips are intended for use in procedures involving ligation of vessels or tissue structures.

70


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



Surgeons should apply the appropriate size clip for the size of the vessel or tissue structures to be ligated such that the clip completely encompasses the vessel or tissue structure.

**6. Summary of Technological Characteristics**

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

71



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

Pages 65 through 66 redacted for the following reasons:
- - - - - - - - - - - - - - - - - - - - - - - - - - - -
(b)(4)

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

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 021808

Reviewer: Dlaurie Bernato

Division/Branch: DGRND/PRSB

Device Name: Weck Hem-o-lok Automatic Ligating Clip applier

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

| | YES | NO | |
|---|---|---|---|
| 1. Is Product A Device | ✓ | | If NO = Stop |
| 2. Is Device Subject To 510(k)? | ✓ | | If NO = Stop |
| 3. Same Indication Statement? | ✓ | | If YES = Go To 5 |
| 4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness? | | | If YES = Stop NE |
| 5. Same Technological Characteristics? | ✓ | | If YES = Go To 7 |
| 6. Could The New Characteristics Affect Safety Or Effectiveness? | | | If YES = Go To 8 |
| 7. Descriptive Characteristics Precise Enough? | ✓ | | If NO = Go To 10<br>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

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

1. Intended Use:

Weck Hem-O-Lok Automatic Ligating Clip Appliers are indicted for use as delivery devices for Hem-o-lok non-absorbable polymer ligating clips. Hem-o-lok ligating clips are intended for use in procedures involving ligation of vessels or tissue structures. Surgeons should apply the appropriate size clip for the size of the vessel or tissue structures to be ligated such that the clip completely encompasses the vessel or tissue structure.

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

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

   The ligating clips in this device are single use, sterile, prescription, life-supporting and sustaining, long-term implant. They are biocompatible and are made of polylactin.

**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: Products are the same, SE

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

7

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

# 510(K) MEMORANDUM

**TO:** **K021808**

**FROM:** D. Laurie Bernato
ODE/DGRND/Plastic and Reconstructive Surgery Devices Branch

**DATE:** August 12, 2002

**SUBJ:** Weck Hem-O-Lok Automatic Ligating Clip Applier

**Recommendation:**
Procode: 79 FZP
Class: II
Regulation Number: 878.4300
Regulation Name: Ligating Clip

**REVIEW:**

1. **Does the product contain drugs or biologicals? If yes, what is the drug/biologic.**
   This product does not contain a drug or biologic.

**2. Indication and/or Intended Use Statement**

**Subject Device**
Weck Hem-O-Lok Automatic Ligating Clip Appliers are indicted for use as delivery devices for Hem-o-lok non-absorbable polymer ligating clips. Hem-o-lok ligating clips are intended for use in procedures involving ligation of vessels or tissue structures. Surgeons should apply the appropriate size clip for the size of the vessel or tissue structures to be ligated such that the clip completely encompasses the vessel or tissue structure.

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

**Predicate Devices**
Weck Closure System's Hem-O-Lok® Ligation Clips (K902108-original submission-medium size clips: K 922186- addition of small and large size clips; K941972- change in ownership: K982941 and K982944- change in materials and labeling; K993157- change in indications and contraindications; K003337-promotion for specific operating procedures; 79FZP) Intended for use in procedures involving ligation of vessels or tissue structures. Surgeons should apply the appropriate size clip for the size of the vessel or tissue structure to be ligated such that the clip completely encompasses the vessel or tissue structure.

**Discussion of equivalency**



4

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

The subject and predicate devices have the same indication statements.

*3.* **Technological Characteristics (Design, Materials, Sizes, etc.)**

**Subject Device**

This device is a sterile, single use, automatic clip applier containing 15 Hem-o-lok ligating clips and a bright orange last clip lockout/indicator. The automatic applier is a delivery service for the non-absorbable clips cleared by the FDA under K902108. This applier consists of a handle, shaft containing 15 locking polymer clips and jaw.

Two models of the proposed device will be available. The first model is intended for endoscopic application of medium large size clips and employs a pistol-grip handle. The overall lenfth of the device is 44 cm ( 17.3 inches) with a working length of 29.7 cm (11.7 inches). The endoscopic device is designed for use down a 5 mm cannula and includes a knob to allow 360$^{o}$ rotation of the applier shaft for jaw positioning using the index finger of the gripping hand,

The second model is intended for open surgery application of large size clips, and employs a ring handle scissor-type grip. The overall length of the open surgery device is 35 cm (13.8 inches) with a working length of 20.1 cm (7.9 inches).

The medium-large endo clip is 5.5 mm while the large, when open, is 7.3 mm.

(b) (4) [redacted]

**Predicate Device**

Design:

Weck Closure System's Hem-O-Lok® Ligation Clips (K993157- 79FZP*)* This clip is a manually applied hemostatic clip intended to aid healing. The clip is nonabsorbable. The clips are housed in a cartridge and packaged in a rigid plastic blister with Tyvek coated lidding which is sold sterile.

Materials:

Polyacetal

**Discussion of equivalency**

There are no new technological characteristics that would affect safety and effectiveness.

2. **Comparitive Performance Data (in vitro, animal and/or clinical)**

**Safety Data**

(b) (4) [redacted]

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

9

(b) (4) [redacted]

Biocompatibility testing- The sponsor demonstrated that all materials with direct patient contact were biocompatible.

**Predicate Device**

Weck Closure System's Hem-O-Lok® Ligation Clips (K993157

(b) (4) [redacted]

**Effectiveness Data**

**Subject Device**

Reliability Testing

(b) (4) [redacted]

**Discussion of Equivalency**

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

These devices are substantially equivalent in their safety and effectiveness.

5. **Sterilization**

   Method – ethylene oxide cycle

(b) (4)

[redacted]

6. **Labeling**

   **Prescription**

   **Package Insert (part 3)**

   **Carton/Pouch Labels (page 3-3 )**

7. **Claims**

   The claims in the labeling are consistent with similar devices.

8. **Has sponsor provided all administrative requirements?**
   - Truthful and Accurate Statement (Page 8-1 )
   - 510(k) Summary (Page 9-1 to9-2)
   - Indication for Use Page (Page 7-1)

9. **Summary**

   Both the devices contain ligating clips that are in same in material and sizes. The clip appliers are Class I, exempt.

10. **Contact History/Requests for More Information:**

    None

8/12/02

Name — Date

Plastic and Reconstructive Surgery Devices Branch





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

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

510(k) Number: K021808

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

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

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

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

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

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

* - May not be applicable for Special 510(k)s.
** - Required for Class III devices, only.
*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

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

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

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

| | Present | Inadequate or Missing |
|---|---|---|
| For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.) | | |
| For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE **Required Elements for a Declaration of Conformity to a Recognized Standard,** which is posted with the 510(k) boilers on the **H drive.**] | | |
| For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device. | | |
| For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device. | | |
| For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence. | | |
| Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence. | N/A | |

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

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

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

*Items with checks in the "Present but Deficient" column require additional information from the sponsor. Items with checks in the " Missing" column must be submitted before substantive review of the document.*

Passed Screening ✓ Yes ____ No
Reviewer: D Laurie Bernato 8/12/02
Concurrence by Review Branch: ______

Date: 8/14/02

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

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

# *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

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

8/13/02

Memorandum DXK

From: Reviewer(s) - Name(s) Dhanvie Bennett

Subject: 510(k) Number K021808

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

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.

| | | |
|---|---|---|
| De Novo Classification Candidate? | ☐ YES | ☐ NO |
| ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.) | | |
| Is this device subject to Postmarket Surveillance? | ☐ YES | ☑ NO |
| Is this device subject to the Tracking Regulation? | ☐ YES | ☑ NO |
| Was clinical data necessary to support the review of this 510(k)? | ☐ YES | ☑ NO |
| Is this a prescription device? | ☑ YES | ☐ NO |
| Was this 510(k) reviewed by a Third Party? | ☐ YES | ☑ NO |
| Special 510(k)? | ☐ YES | ☑ NO |
| Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers | ☐ YES | ☑ NO |

This 510(k) contains:

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

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

☐ The required certification and summary for class III devices

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

Animal Tissue Source ☐ YES ☐ NO

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

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

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

79 FZP, Class II, 878.4300, Implantable Clip

Review: [signature], Acting BC (PRSB) 8/14/02
(Branch Chief) (Branch Code) (Date)

Final Review: [signature] 8/14/02
(Division Director) (Date)

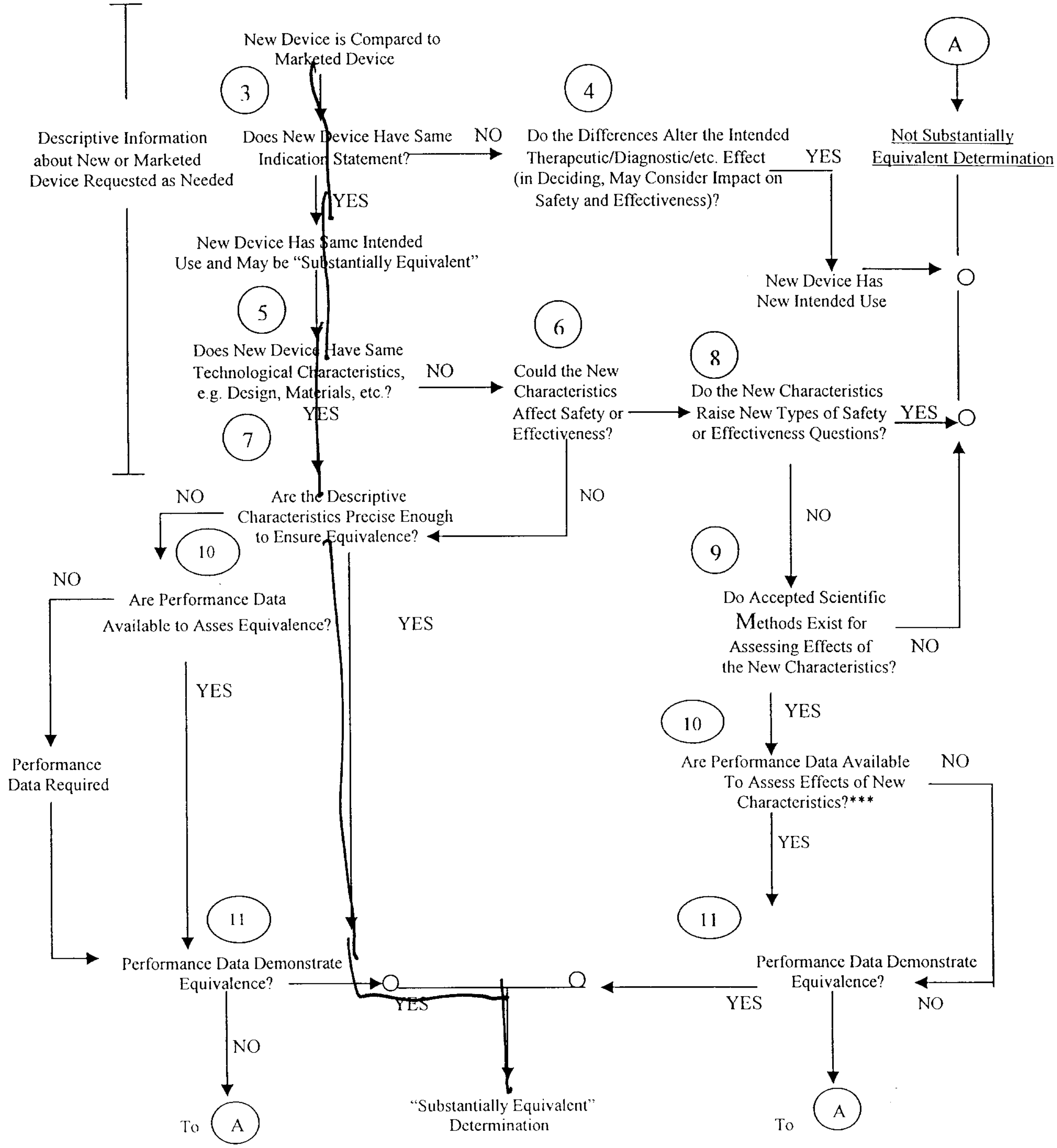
Revised:8/17//99

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

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




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

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

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

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