MICROLINE SURGICAL

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K122086

Page 1 of 3

510(k) Summary

Contact Person: Dean Ciporkin, Sr. Director of Regulatory Affairs and Quality Assurance

Submitted By: Microline Surgical
800 Cummings Center,
Beverly, MA 01915
Tel: 978-922-9810
Fax: 978-922-9209

AUG 23 2012

Common Name: Electrosurgical System

Device Product Code: GEI

Classification Name: Electrosurgical Cutting and Coagulation Device and accessories
21 CFR § 787.4400

Device Panel: General Surgery/Restorative Devices

Date Prepared: August 17, 2012

Proprietary Name: MiSeal™ Reposable Thermal Ligating Shears

Device Classification: Class II

Predicate Device: This product is similar in design, composition, and function to the:
Starion Instruments Thermal Ligating Shears (K062257) cleared October 10, 2006

Establishment Registration Number: 1223422

Device description and technological Characteristics:

The MiSeal Reposable Thermal Ligating Shears system consists of the following:

MiSeal Reusable Handpiece
MiSeal Thermal Ligating Shears Kit
Universal Power Supply 200-006R

The MiSeal Reposable Thermal Ligating Shears are designed to provide thermal ligation and division in various surgical procedures. The MiSeal Reposable Thermal Ligating Shears consist of a reusable handpiece with a disposable tip. The device has heating elements at the distal tip which are activated by a finger switch located on

the handpiece of the device. The MiSeal Reposable Thermal Ligating Shears are designed to allow the surgeon control of the heating element power of the device in order to accommodate the individual patient anatomy. An instrument cord connects the handpiece to the dedicated Microline Surgical Universal Power Supply K070871.

The MiSeal Reposable Handpiece is supplied non-sterile in a foam cavity placed in a fiberboard carton and is for multiple patient uses following cleaning and steam sterilization procedures performed per the provided Instructions for Use. The handpiece can be used multiple times if cleaning and sterilization procedures are followed. The MiSeal Disposable Kit (the functional instrument Tip and power cable portion of the applied part of the system) is supplied sterile in a die-cut chipboard Packaging Insert and Tyvek/Mylar pouch and is labeled for single use only. The tip is intended to be used by a trained physician for a single patient use in open general surgery, open vascular surgery, and laparoscopic surgical procedures.

The MiSeal single use power cable is connected to the handle of the instrument handpiece and terminates at the electrical connection of the Universal Power Supply. The system power supply is supplied non-sterile for reusable use outside the sterile field.
The MiSeal device incorporates Hi and Low heating modes that are used to coagulate and cut soft tissue. The heating elements in the disposable tip are activated by a physician controlled finger switch located on the handpiece of the device. The MiSeal device is intended to provide general purpose dissection, spreading, and grasping of soft tissue during minimally invasive or open surgical procedures.

To coagulate and cut tissue, the physician grasps the desired tissue between the jaws of the MiSeal Reposable Thermal Ligating Shears and gently squeezes the thumb trigger and handpiece to close the jaws. Depressing the finger switch and squeezing the thumb trigger activates the heating elements in the distal tip. An audible low frequency tone accompanies the activation of the heating element in the variable mode to notify the physician the power is being applied. An audible high frequency tone will accompany the activation of the heating element in High power mode. Depressing the finger switch on the top of the handle provides either Hi or Low heating mode. Generally, a lower UPS output setting improves the sealing capabilities and lengthens the time required to divide tissue. Conversely, a higher output setting reduces the time to divide tissue and may result in decreased vessel seal integrity

Indications for Use:

The MiSeal Reposable Thermal Ligating Shears are intended for the simultaneous cutting and cauterization of soft tissue during surgery, and cutting of natural or synthetic, nonmetallic sutures during surgery.

Performance Testing:

Preclinical and performance tests were performed to assure the MiSeal Reposable Thermal Ligating Shears functioned as intended and met all product specifications. Sufficient data was generated and analyzed to prove that the MiSeal Reposable Thermal Ligating Shears was substantially equivalent to the predicate device.

Summary:
The information provided demonstrates that the MiSeal Reposable Thermal Ligating Shears is substantially equivalent to the Starion Instruments Thermal Ligating Shears in function, construction, intended use and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Microline Surgical
% Mr. Dean Ciporkin
Sr. Director of Regulatory Affairs and Quality Assurance
800 Cummings Center, Suite 166T
Beverly, Massachusetts 01915

AUG 23 2012

Re: K122086
Trade/Device Name: MiSeal Reposable Thermal Ligating Shears
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 13, 2012
Received: July 16, 2012

Dear Mr. Ciporkin:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122086

Device Name: MiSeal Reposable Thermal Ligating Shears

Indications for Use:

The MiSeal Reposable Thermal Ligating Shears are intended for the simultaneous cutting and cauterization of soft tissue during surgery, and cutting of natural or synthetic, nonmetallic sutures during surgery.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden -MAM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K122086

K122086/OR V.1

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Microline Surgical
% Mr. Dean Ciporkin
Sr. Director of Regulatory Affairs and Quality Assurance
800 Cummings Center, Suite 166T
Beverly, Massachusetts 01915

AUG 23 2012

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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.

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Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122086

Device Name: MiSeal Reposable Thermal Ligating Shears

Indications for Use:

The MiSeal Reposable Thermal Ligating Shears are intended for the simultaneous cutting and cauterization of soft tissue during surgery, and cutting of natural or synthetic, nonmetallic sutures during surgery.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden mam

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K122086

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name GEORGE J. MATTAMAL

Subject: 510(k) Number K122086

To: The Record

Please list CTS decision code SE

- ☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- ☐ Hold (Additional Information or Telephone Hold).
- ☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NS	NSE no response
☐	NL	NSE for lack of performance data AND no response
☐	NM	NSE pre-amendment device call for PMAs (515i)
☐	NC	NSE post-amendment device requires PMAs
☐	NH	NSE for new molecular entity requires PMA
☐	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III?			X
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			X
Is this a combination product? (Please specify category N, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			X
Is clinical data necessary to support the review of this 510(k)?			X
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was			

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)

Does this device include an Animal Tissue Source?

All Pediatric Patients age<=21

Neonate/Newborn (Birth to 28 days)

Infant (29 days -< 2 years old)

Child (2 years -< 12 years old)

Adolescent (12 years -< 18 years old)

Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*

Regulation Number	**Class***	**Product Code**
878.4400	II	GEI

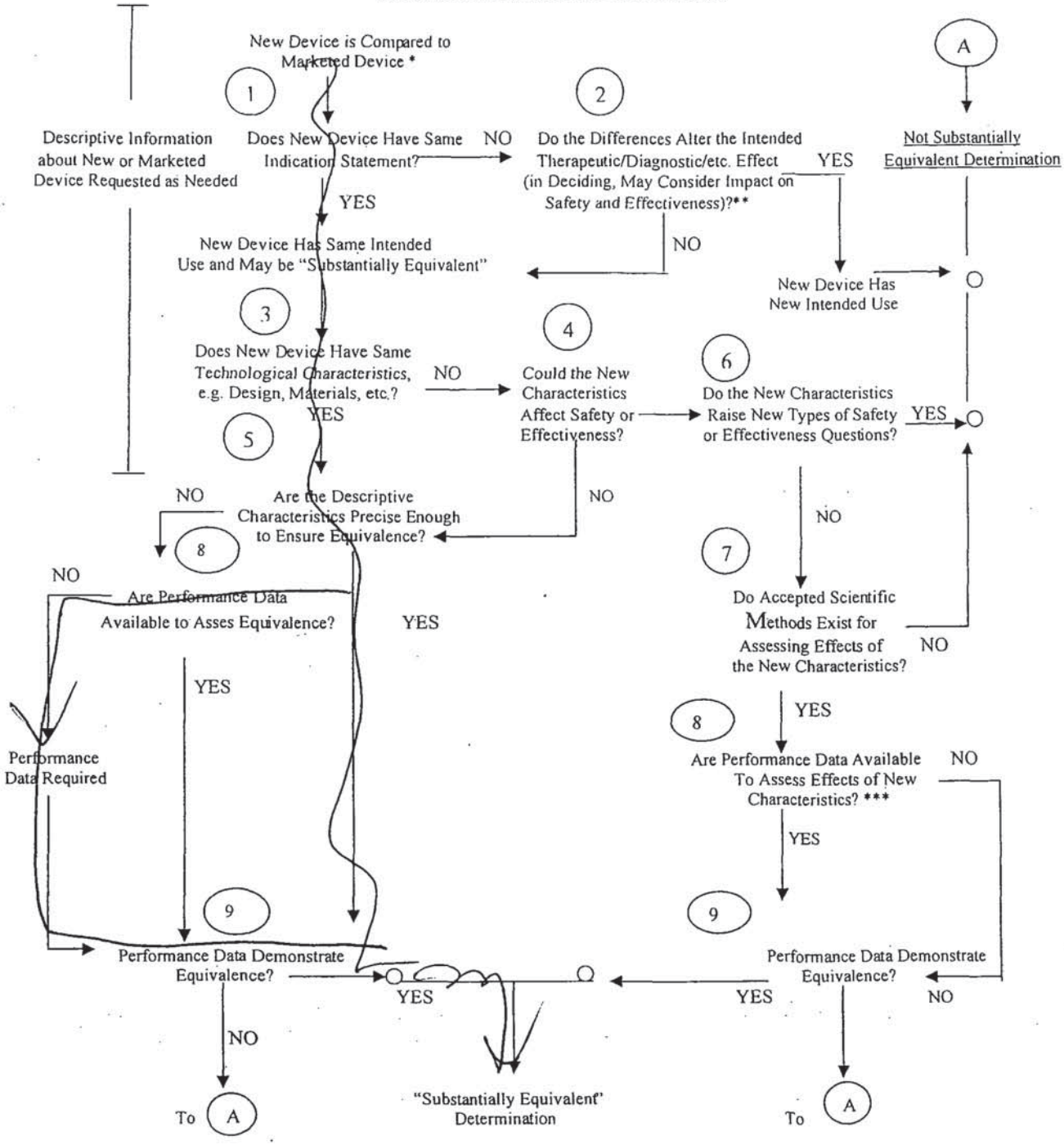
(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: Neil R.P. Ogden (Branch Chief) GSDB (Branch Code) 8/22/12 (Date)

Final Review: (Division Director) (Date) 9/26/12

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.

MEMO TO THE RECORD
510(k) REVIEW
K122086

DATE: August 20, 2012 **OFFICE: HFZ-410**
FROM: George J. Mattamal, Ph.D **DIVISION: DSORD/GSDB**

DEVICE NAME: MiSeal Reposable Thermal Ligating Shears

COMPANY NAME: Microline Surgical, Inc.

CONTACT: Mr. Dean E. Ciporkin, Sr. Director of Quality Regulatory Affairs.
(Tel. No. 978-867-1758 & Fax. 978-922-9209)
E-mail: dciporkin@microlinesurgical.com
and
Mr. Bill McCallum, Regulatory Affairs Manager
(Tel. No. 978-867-1726 & Fax. 978-922-9209)
E-mail: bmccallum@microlinesurgical.com

DEVICE DESCRIPTION and PERFORMANCE: The sponsor has submitted the subject 510 (K), K22086 submission, to notify FDA that their company intends to market the proposed device, MiSeal Reposable Thermal Ligating Shears, which is intended to be used as its predicate K062257 device "for the simultaneous cutting and cauterization of soft tissue during surgery, and cutting of natural or synthetic, nonmetallic sutures during surgery". Specifically, the subject device, MiSeal Reposable Thermal Ligating Shears, is a hand-held surgical instrument and its reusable hand piece consists of 4 different shaft lengths, 14cm, 23 cm, 35 cm, and 45 cm and are supplied non-sterile, but to be used sterile prior to use.

The term"**Reposable"** was used by the sponsor, Microline Surgical, since the device was derived from using a reusable handpiece and a disposable tip. (i.e., a re-usable handpiece combined with a disposable tip). The subject device kit, as its predicate device, also consisting of a 5 mm curved jaw tip and instrument cord, supplied single patient use, sterile. The sponsor has claimed their device SE to exactly similar type of predicate device, the Starion Instrument Corporation's Thermal Legating Shears (K062257). It should be noted that at present, the Starion Instrument Corporation's Thermal Legating Shears (K062257) is wholly owned by the sponsor, the Microline Surgical and both the subject and predicate K062257 were developed by the Starion Instrument Corporation.

Although, both the subject and predicate K062257 devices have the **same intended use** and very similar design and function, the following modifications are being incorporated (that differentiate from predicate) include the following: A reusable handpiece, a single-use disposable tip, a rocker switch for tip installation, a flush port and a single-use disposable-cable. For example the predicate K062257 is supplied sterile for single user whereas the subject device has a reusable hand piece, and a sterile single use tip that is threaded on the headpiece and disposed of after single patient use.

Also included in the kit is a previously cleared sterile single use electrical cable that connects the subject device to the Universal Power Supply (K070871). Tips and cables are intended to be assembled to the handle prior to use. The disposable pack is sterilized via a validated gamma irradiation process. The predicate K062257 device has **the same tip and cable** as the subject device, the only difference is the predicate tip and cable is permanently attached because the whole device is sold sterile, for single patient use. However, as explained above, the subject device, MiSeal Reposable Thermal Ligating Shears, has a reusable handpiece, and a sterile single use tip that is treaded on the handpiece and disposed of after single patient use.

The subject device, MiSeal Reposable Thermal Ligating Shears, incorporates Hi and Low heating modes that are used to coagulate and cut soft tissue. The heating elements in the disposable tips are activated by a physician controlled finger switch located on the handpiece of the device. The subject device is intended to provide general purpose dissection, spreading, and grasping of soft tissue during minimally invasive or open surgical procedure.

In surgical setting, in order to coagulate and cut tissue, the physician grasps the desired tissue between the jaws of the subject device and gently squeezes the thumb trigger and handpiece to close the jaws. Depressing the finger switch and squeezing the thumb trigger activates the heating elements in the distal tip. An audible low frequency tone accompanies the activation of the heating elements in the variable mode to notify the physician the power is being applied. An audible high frequency tone will accompany the activation of the heating elements in high power mode. Depressing the finger switch on the top of the handle provides either Hi or Low heating mode. According to the sponsor, generally, a lower UPS output setting improves the sealing capabilities and lengthens the time required to divide tissue. Conversely, a higher output setting reduces the time to divide tissue and may result in decreased vessel and integrity.

The sponsor (**Mr. Dean E. Ciporkin**) was contacted on August 16, 17, and 20, 2012 and discussed about the device and requested the following:

> Please provide a **revised** Intended use statement form, **revised** Premarket notification truthful and accurate statement form, and a **revised** Summary form by deleting the word "sealing",

The required information was received on 8/17/12 and hard copies of the same will follow later.

The sponsor has provided engineering drawings with photos and physical and general specifications of subject device, MiSeal Reposable Thermal Ligating Shears. Also, the sponsor has provided a very detailed substantial equivalence comparison report with a side by side comparison describing device's intended use, physical characteristics, disposal instructions, sterility, design for safety, materials, energy source etc. of the subject device and the predicate device such as their own, the Starion Instrument corporation's Thermal Legating Shears (K062257).The subject device is very similar to the predicate device.

The sponsor has performed detailed studies on pre-clinical and performance tests such as the design verification activities tests on the subject device and compared to the predicate device, the Station Instrument corporation's Thermal Legating Shears (K062257) These tests were performed to

assure that the subject device, MiSeal Reposable Thermal Ligating Shears, was substantially equivalent to the predicate device. Also the sponsor has performed an animal study (**a supplemental testing**) to evaluate the equivalency of subject device VS the predicate device. This additional bench top testing was performed to gather data to differentiate **BUST PRESSURE** data of both subject and predicate devices. Freshly harvested porciline caroid artery VESSELS were used for in vitro testing at the devices. Also a summary of results from the report "Burst Pressure and sealing data overview of subject and predicate device has been provided (Please see page 623 of the submission). According to the sponsor the **rationale for the Burst pressure testing is** that in a near future, the sponsor will be sending another 510 (k) for the intended use for "**SEALING**"

Electrosurgical Testing: The sponsor has certified (and performed) that the subject device has been designed and tested to conform to the applicable sections of the following standard:

- IEC 60601-1 and IEC 60601-1-2, Medical Electrical Equipment Part 1: General Requirements for Safety.

BIOCOMBATABILITY TESTING: There is no biocompatibility issue associated with the subject device, since it is constructed exactly of the **same materials** as of its predicate device, the Starion Instrument Corporation's Thermal Legating Shears (K062257). There is no safety concern with this proposed device.

1. **Administrative Requirement**

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription)	X		
Truthful and Accuracy Statement concern with this proposed device.	X		
510(k) Summary	X		
Standards Form		X	

II. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?		X	
*Is the device sterile? The disposable electrode insertion device (EID) is supplied sterile for single use patient use only.	X		
*Is the device reusable (not reprocessed single use)? cooling system hand piece are supplied non-sterile and are re-usable and	X		

* Please note that the subject device has reusable handpiece and a single use- disposable tip

III. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	X		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?	X		If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?	X		If **NO** = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: **SE**

INTENDED USE/INDICATIONS FOR USE: The subject device, MiSeal Reposable Thermal Legating Shears, is intended "for the simultaneous cutting and cauterization of soft tissue during surgery, and cutting of natural or synthetic, nonmetallic sutures during surgery". This intended use is SE (**Chart 3**) its predicate device, such as their own, the Starion Instrument corporation's Thermal Legating Shears (K062257).

PREDICATE DEVICE (S): The subject device, MiSeal Reposable Thermal Ligating Shears, is SE (**Chart 3**) in design configuration, technological characteristics (**Chart 5**), function, and intended use to its predicate devices, such as their own, the Starion Instrument corporation's Thermal Legating Shears (K062257)

STARILITY, PACKAGING, AND LABELING: The subject device, MiSeal Reposable Thermal Ligating Shears contains a **re-usable handpiece combined with a disposable tip**. Accordingly, The term"Reposable" was used by the sponsor, Microline Surgical, since the device was derived from using a reusable handpiece and a disposable tip. (i.e., a re-usable handpiece combined with a disposable tip).

The disposable, sterile and single use part of the device, the tip, will be sterilized using gamma radiation to a minimum dose of 25 kGy and a maximum dose of 40 kGy. The gamma sterilization will be validated in accordance with clause 9, Method V Dmax – Substantiation of 25 kGy as the sterilization dose in ISO 11137-2:2006, to achieve a sterility assurance level (SAL of 10^{-6}). The re-usable handpiece will be thoroughly cleaned (such as using detergent, using a syringe, 60ml of

reverse osmosis /de-ionized process, bioburden testing,etc.) prior to steam sterilization. Validation of the team sterilization of the reusable hand piece is to a SAL of 10^{-6} The sponsor has provided all the cleaning procedures in the draft labeling such as:

- Prior to sterilization, the instrument must be thoroughly cleaned
- The instrument must be wrapped
- The following cycle must be used:
    1. gravity Cycle: 4 minutes ≥ 270°F (132°C)
    2. Pre-Vacuum Cycle : 4 minutes ≥ 270°F (132°C)

The sponsor has provided an IFU (draft labeling) for the device per "the **Guidance Document for General Surgical Electrosurgical Devices**" that contains, all the necessary cleaning, washing for the reusable handle, and description/Indications, Contraindications, Warnings, Precautions, and Instruction of for Use, etc. And the draft labeling is found to be satisfactory. There is no safety concern with this proposed device.

SAFETY AND EFFECTIVENESS INFORMATION & TRUTHFUL AND ACCURATE STATEMENT: The sponsor has provided 1) a **revised** summary of safety and effectiveness information and 2) a **revised** truthful and accurate statement about the device.

RECOMMENDATION: The subject device, MiSeal Reposable Thermal Ligating Shears, is SE (**Chart 7**) to its predicate device, such as their own, the Starion Instrument corporation's Thermal Legating Shears (K062257). The device is associated with electrosurgical surgery and is categorized as 79 GEI (Electrosurgical Device, Cutting & Coagulation & accessories). And the device is Class II based on 21 CFR 878.4400

George J. Mattamal 8/20/12

George J. Mattamal, Ph. D., **Date**
General and Surgery Devices Branch
Division of Surgical, Orthopedic and Restoratives Devices.

Neil Ogden I concur with SE. 8/22/12

Neil R. P. Ogden, M.S./Chief **Date**
General and Surgery Devices Branch
Division of Surgical, Orthopedic and Restorative Devices.

CONTACT HISTORY: The sponsor (**Mr. Dean E. Ciporkin)** was contacted on August 16, 17, and 20, 2012 and discussed about the device and requested to provide AI. The required AI was received as e-mailed materials. And the hard copies of the same will follow later.

Mattamal, George

From: Dean Ciporkin [dciporkin@microlinesurgical.com]
Sent: Friday, August 17, 2012 2:26 PM
To: Mattamal, George
Cc: Dean Ciporkin; Bill McCallum
Subject: Microline's 510(k) #K122086

Attachments: Document.pdf

Document.pdf (3 MB)

Dr. Mattamal,

Attached are our changes to the documents you requested.

Best regards,

Dean E. Ciporkin | Sr. Director of Regulatory Affairs & Quality Assurance
Microline Surgical, Inc.
800 Cummings Center, Suite 166T
Beverly, MA 01915, USA
Direct: 978.867.1758 | Fax: 978.922.9209 |
dciporkin@microlinesurgical.com

Indications for Use

510(k) Number (if known): K122086

Device Name: MiSeal Reposable Thermal Ligating Shears

Indications for Use:

The MiSeal Reposable Thermal Ligating Shears are intended for the simultaneous cutting and cauterization of soft tissue during surgery, and cutting of natural or synthetic, nonmetallic sutures during surgery.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

MICROLINE™
SURGICAL

800 Cummings Center, Suite 166T
Beverly, MA 01915, USA
Tel: 978.922.9810
Fax: 978.922.9209
Web: www.microlinesurgical.com

Premarket Notification Truthful And Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Regulatory Manager of Microline Surgical, Inc., 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.

Wm Shaw McCallum

August 17, 2012

K122086

MICROLINE SURGICAL

800 Cummings Center, Suite 166T
Beverly, MA 01915, USA
Tel: 978.922.9810
Fax: 978.922.9209
Web: www.microlinesurgical.com

510(k) Summary

Contact Person: Dean Ciporkin, Sr. Director of Regulatory Affairs and Quality Assurance

Submitted By: Microline Surgical
800 Cummings Center,
Beverly, MA 01915
Tel: 978-922-9810
Fax: 978-922-9209

Common Name: Electrosurgical System

Device Product Code: GEI

Classification Name: Electrosurgical Cutting and Coagulation Device and accessories
21 CFR § 787.4400

Device Panel: General Surgery/Restorative Devices

Date Prepared: August 17, 2012

Proprietary Name: MiSeal™ Reposable Thermal Ligating Shears

Device Classification: Class II

Predicate Device: This product is similar in design, composition, and function to the:
Starion Instruments Thermal Ligating Shears (K062257) cleared October 10, 2006

Establishment Registration Number: 1223422

Device description and technological Characteristics:

The MiSeal Reposable Thermal Ligating Shears system consists of the following:

MiSeal Reusable Handpiece
MiSeal Thermal Ligating Shears Kit
Universal Power Supply 200-006R

The MiSeal Reposable Thermal Ligating Shears are designed to provide thermal ligation and division in various surgical procedures. The MiSeal Reposable Thermal Ligating Shears consist of a reusable handpiece with a disposable tip. The device has heating elements at the distal tip which are activated by a finger switch located on

the handpiece of the device. The MiSeal Reposable Thermal Ligating Shears are designed to allow the surgeon control of the heating element power of the device in order to accommodate the individual patient anatomy. An instrument cord connects the handpiece to the dedicated Microline Surgical Universal Power Supply K070871.

The MiSeal Reposable Handpiece is supplied non-sterile in a foam cavity placed in a fiberboard carton and is for multiple patient uses following cleaning and steam sterilization procedures performed per the provided Instructions for Use. The handpiece can be used multiple times if cleaning and sterilization procedures are followed. The MiSeal Disposable Kit (the functional instrument Tip and power cable portion of the applied part of the system) is supplied sterile in a die-cut chipboard Packaging Insert and Tyvek/Mylar pouch and is labeled for single use only. The tip is intended to be used by a trained physician for a single patient use in open general surgery, open vascular surgery, and laparoscopic surgical procedures.

The MiSeal single use power cable is connected to the handle of the instrument handpiece and terminates at the electrical connection of the Universal Power Supply. The system power supply is supplied non-sterile for reusable use outside the sterile field.
The MiSeal device incorporates Hi and Low heating modes that are used to coagulate and cut soft tissue. The heating elements in the disposable tip are activated by a physician controlled finger switch located on the handpiece of the device. The MiSeal device is intended to provide general purpose dissection, spreading, and grasping of soft tissue during minimally invasive or open surgical procedures.

To coagulate and cut tissue, the physician grasps the desired tissue between the jaws of the MiSeal Reposable Thermal Ligating Shears and gently squeezes the thumb trigger and handpiece to close the jaws. Depressing the finger switch and squeezing the thumb trigger activates the heating elements in the distal tip. An audible low frequency tone accompanies the activation of the heating element in the variable mode to notify the physician the power is being applied. An audible high frequency tone will accompany the activation of the heating element in High power mode. Depressing the finger switch on the top of the handle provides either Hi or Low heating mode. Generally, a lower UPS output setting improves the sealing capabilities and lengthens the time required to divide tissue. Conversely, a higher output setting reduces the time to divide tissue and may result in decreased vessel seal integrity

Indications for Use:

The MiSeal Reposable Thermal Ligating Shears are intended for the simultaneous cutting and cauterization of soft tissue during surgery, and cutting of natural or synthetic, nonmetallic sutures during surgery.

Performance Testing:

Preclinical and performance tests were performed to assure the MiSeal Reposable Thermal Ligating Shears functioned as intended and met all product specifications. Sufficient data was generated and analyzed to prove that the MiSeal Reposable Thermal Ligating Shears was substantially equivalent to the predicate device.

Summary:

The information provided demonstrates that the MiSeal Reposable Thermal Ligating Shears is substantially equivalent to the Starion Instruments Thermal Ligating Shears in function, construction, intended use and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

July 17, 2012

MICROLINE SURGICAL, INC
800 CUMMING CENTER
SUITE 166T
BEVERLY, MASSACHUSETTS 01915
ATTN: WILLIAM MCCALLUM

510k Number: K122086

Received: 7/16/2012

Product: THERMAL LIGATING SHEARS

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) 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.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm
for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

Grayson, Giovanna *

From: Microsoft Outlook
To: 'bmccallum@microlinesurgical.com'
Sent: Tuesday, July 17, 2012 9:33 AM
Subject: Relayed: ack letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'bmccallum@microlinesurgical.com'

Subject: ack letter

Sent by Microsoft Exchange Server 2007

Grayson, Giovanna *

From: Grayson, Giovanna *
Sent: Tuesday, July 17, 2012 9:32 AM
To: 'bmccallum@microlinesurgical.com'
Subject: ack letter
Attachments: image002.png

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

July 17, 2012
MCCALLUM
WILLIAM
MICROLINE SURGICAL, INC
800 CUMMING CENTER
SUITE 166T
BEVERLY, MASSACHUSETTS 01915
ATTN: WILLIAM MCCALLUM

510k Number: K122086
Received: 7/16/2012
Product: THERMAL LIGATING SHEARS

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Sincerely,

510(k) Staff

MiSeal Reposable Thermal Ligating Shears

Microline Surgical, Inc.
800 Cummings Center, Suite 166T
Beverly, MA 01915

MiSeal Reposable Thermal Ligating Shears

1. Medical Device User Fee Cover Sheet (Form FDA 3601)
2. CDRH Premarket Review Submission Cover Sheet
3. 510(k) Cover Letter
4. Indications for Use Statement
5. 510(k) Summary or 510(k) Statement
6. Truthful and Accuracy Statement
7. Class III Summary and Certification
8. Financial Certification or Disclosure Statement
9. Declaration of Conformity and Summary Reports
10. Executive Summary
11. Device Description
12. Substantial Equivalence Discussion
13. Proposed Labeling
14. Sterilization and Shelf Life
15. Biocompatibility
16. Software
17. Electromagnetic Compatibility and Electrical Safety
18. Performance Testing – Bench
19. Performance Testing – Animal
20. Performance Testing – Clinical
21. Standards Data Reports

NOTE: For pagination please see the accompanying "Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

based on
Guidance for Industry and FDA Staff
Format for Traditional and Abbreviated 510(k)s[2]

Title	Related Information	Page	N/A
MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet[3]	7	
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Cover Sheet[4]	9	
510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	16	
Indications for Use Statement	Device Advice "Content of a 510(k)" Section D[5]	22	
510(k) Summary or 510(k) Statement	Device Advice "Content of a 510(k)" Section E[6]	24	
Truthful and Accuracy Statement	Device Advice "Content of a 510(k)" Section G[7]	27	
Class III Summary and Certification	Class III Summary and Certification Form[8]	29	
Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators[9] FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators[10] Financial Disclosure by Clinical Investigators[11]	31	
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	Use of Standards in Substantial Equivalence Determinations[12] FDA Standards program[13] Declaration of conformity[14] Required Elements for Declaration of Conformity to Recognized Standard[15]	33	
Executive Summary	See section 10 in Chapter II of "Guidance for Industry and FDA	35	

	Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005		
Device Description	See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	37	
Substantial Equivalence Discussion	Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3)[16]	47	
Proposed Labeling	Device Advice " Content of a 510(k)" Section H[17]	63	
Sterilization/Shelf Life	Updated 510(k) Sterility Review Guidance (K90-1)[18] For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices[19]	80	
Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"[20]	536	
Software	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices[21]	579	
Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program[22] See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)	581	
Performance Testing – Bench	See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and	599	

	Abbreviated 510(k)s" updated November 17, 2005	
Performance Testing – Animal	See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	610
Performance Testing – Clinical	See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators[23] FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators[24]	625
FORM FDA 3654, Standards Data Report for 510(k)s[25]	**Standards Data Report Form – Form 3654** 1. No standard used - **No Standards Form Required** 2. Declaration of Conformity – **Yes Standards Form Required** 3. Standard but no declaration – **Yes Standards Form Required**	627
Kit Certification	Device Advice[26]	N/A

1

Medical device User Fee Cover Sheet

FDA U.S. Food and Drug Administration — Department of Health and Human Services

Confirmation

YOUR PAYMENT IDENTIFICATION NUMBER IS: MD 6062646-956733

Your Cover Sheet has been submitted electronically. You must print and sign the hard copies. Include one in each copy of your application and include a copy with your payment.

Thank you for visiting the FDA User Fee Website. As part of our efforts to improve customer service, we would like to hear from you.
Please 'click here' to submit a survey. This will only take about 2 minutes to complete.

Coversheet		Creation Date	Last Update Date	
Medical Device User Fee and Modernization Act (Print/View Final Coversheet)	1	05-JUL-2012	05-JUL-2012	Net: $4,049.00

Total: $4,049.00

Customer Information

Customer: MIRCOLINE SURGICAL INC
William McCallum
978-867 1726
bmccallum@microlinesurgical.com

Applicant Contact Information

Bill To: William McCallum
MIRCOLINE SURGICAL INC
800 CUMMINGS CENTER SUITE 166T
BEVERLY,MA 01915
UNITED STATES

(Pay Now) (Create Another Cover Sheet)

2

CDRH Premarket Review Submissions Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Microline Surgical, Inc.	1223422		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	978 867 1726		
Street Address	**FAX Number *(including area code)***		
800 Cummings Center, Suite 166T	978 867 1787		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Beverly,	Massachussetts	01915	USA
Contact Name			
William McCallum			
Contact Title	**Contact E-mail Address**		
Regulatory Affairs Manager	bmccallum@microlinesurgical.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
N/A			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Street Address	**FAX Number *(including area code)***		
City	**State / Province**	**ZIP Code**	**Country**
Contact Name			
Contact Title	**Contact E-mail Address**		

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site
- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*
- ☐ Response to FDA correspondence:
- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address
- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access
- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final
- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing
- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology
- ☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	GEI	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K062257	Starion Instruments. Corp. Thermal Ligating Shears	Starion Instruments, Corp.
2			
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Electrosurgical cutting and coagulation device and accessories

	Trade or Proprietary or Model Name for This Device		Model Number
1	Thermal Ligating Shears	1	132-136D, 132-132D, 132-133D
2		2	
3		3	
4		4	
5		5	

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

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

Data Included in Submission

☒ Laboratory Testing ☒ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
GEI	21 CFR 878.4400	☐ Class I ☒ Class II
Classification Panel		☐ Class III ☐ Unclassified
79 General and Plastic Surgery		

Indications *(from labeling)*

The MiSeal Reposable Thermal Ligating Shears are intended for the simultaneous cutting and cauterization of soft tissue during surgery, and cutting natural or synthetic, nonmetallic sutures during surgery.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☒ Contract Manufacturer ☐ Repackager / Relabeler

(b)(4)

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☒ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

(b)(4)

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name N/A		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	15223-1	ISO	Medical Devices-Symbols to be used with the medical device labels, labelling and information to be supplies-Part 1: General requirements	First Edition	04/15/2007
2	D4169	ASTM	Standard Practice for Performance Testing of Shipping Containers and Stystems	09	01/01/2019
3	11137-1	ISO	Sterilization of health care products-Radiation-Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices	06	01/01/2006
4	11137-2	ISO	Sterilization of health care products-Radiation-Part 2: Establishing the sterilization dose	06	01/01/2006
5	11137-3	ISO	Sterilization of health care products-Radiation-Part 3: Guidance of dosimetric aspects	06	01/01/2006
6	10993-1	ISO	Biological evaluation of medical devices-Part 1:Evaluation and testing within a risk management process	09	07/12/2012
7	60601-1	IEC	Medical Electrical Equipment-Part 1:General Requirements for Basic Safety and Essential Performance	2nd	01/01/1995

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

	STD's #	STD' s Org	STD's Title	Version	Date
8	60601-1-2	IEC	Medical Electrical Equipment-Part 1-2: General Requirements for Safety-Collateral standard: EMC	2nd	2007
9	F 1980	ASTM	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	07	4/1/2007
10	14971	ISO	Medical devices-Application of risk management to medical devices	07	2007

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510(k) Cover Letter

K122084

MICROLINE™ SURGICAL

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July 13, 2012

FDA CDRH DMC

JUL 16 2012

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center - WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: (510k) Premarket Notification - Microline Surgical MiSeal Thermal Ligating Shears Instrument for Use with the Microline Surgical Universal Power Supply

To Whom It May Concern:

In accordance with Chapter I, Title 21 CFR 807.87, enclosed is the Microline Surgical, Inc. Traditional 510(k) Premarket Notification submission for the Microline Surgical MiSeal Thermal Ligating Shears Instrument. This is the initial Premarket Notification for the Microline Surgical MiSeal Instrument. Per 21 CFR 801.109, Subpart D, the Microline Surgical MiSeal Instrument is intended for prescription use.

The subject Microline Surgical MiSeal Thermal Ligating Shears Instrument is designed with a reusable handpiece and a disposable single use distal tip that attaches to the handpiece. After use, the handpiece is sterilized and the tip is removed and discarded. Together, the reusable handpiece and the disposable distal tip constitute the reposable Microline Surgical MiSeal Instrument. The MiSeal Instrument is available in 14cm, 23cm, 35cm and 45cm shaft lengths.

The subject MiSeal Thermal Ligating Shears Instrument is a reposable version of the predicate device the Thermal Ligating Shears cleared via 510(k) under #K062257, a fully disposable device.

The disposable Thermal Ligating Shears (#K062257) and the reposable MiSeal Thermal Ligating Shears Instrument are designed to be used only with the same Universal Power Supply (UPS) which was cleared via 510(k) under K070871. No design changes were necessary for the UPS as result of the design of the MiSeal Thermal Ligating Shears Instrument.

In this 510(k) the MiSeal instrument is variably referred to as the Hydra instrument, the in-house project name.

The Microline Surgical MiSeal Thermal Ligating Shears Instrument does not contain a drug or a biologic. The Microline Surgical MiSeal Instrument is not an implantable device.

Starion Instruments Corp., which developed the original Thermal Ligating Device, was acquired by Microline Surgical Inc. on April 19, 2009 as a wholly owned subsidiary of Microline Surgical Inc. and subsequently merged on October 3, 2011 with Microline Surgical Inc.

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The reposable MiSeal Thermal Ligating Shears Instrument falls under a regulatory letter to file based on the disposable Thermal Ligating Shears granted clearance on 10/10/2006 via 510(k) #K062257. The rationale for the regulatory letter to file were:

- a surgical instrument intended to be used for simultaneous cutting and cauterization of soft tissue during surgery and cutting natural or synthetic, non-metallic sutures during surgery (same indications for use)
- identical in function, geometry, target population, energy source, and principle of operation
- both used with the Starion Instruments Universal Power Supply (K070871)

The design changes to the original device were documented as such in a "Note to File", per the FDA Guidance document "Deciding When to Submit a 510(k) for a Change to an Existing Device", January 19, 1997. From the Guidance document, it was determined that the design changes were identified as a "Note to File-No 510(k) Needed".

Basis of Submission:

The Microline Surgical MiSeal Thermal Ligating Shears Instrument, like the 510(k) cleared Thermal Ligating Shears, seals by the application of heat to soft tissue interposed between the jaws of the instrument. Once the heating is completed the soft tissue separates. No cutting blade is needed.

The Microline Surgical MiSeal Instrument is not indicated for tubal sterilization or tubal coagulation for sterilization procedures.

The identified predicate device for this Premarket Notification is the:

- Starion Instruments, Thermal Ligating Shears (K062257)

The Microline Surgical MiSeal Thermal Ligating Shears Instrument is identical in design to the predicate device except for the reusable handle design and the single use disposable tip for cost effectiveness.

Microline Surgical intends to submit in the future a Premarket Notification for clearance for a vessel size sealing indication. It is for this reason that Microline is submitting this standalone 510(k) for reposable but otherwise substantially similar device, before proceeding with a future 510(k) submission for a vessel size indication.

Administrative Information:

1. Type of 510(k) Submission: Traditional
2. Device Trade or Proprietary Name: Microline Surgical MiSeal Thermal Ligating Shears
3. 510(k) Submitter: Microline Surgical, Inc.
   800 Cummings Center Suite 166T
   Beverly, MA 01915

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4. Contact Person: Dean E. Ciporkin, Sr. Director of Regulatory Affairs and Quality Assurance

5. Manufacturer: Microline Surgical, Inc.
800 Cummings Center Suite 166T
Beverly, MA 01915

8. Common Name: Electrosurgical System

9. Device Product Code: GEI

10. Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)

11. Device Panel: General Surgery/Restorative Devices

12. Device Classification: Class II

13. Establishment Registration Number: 1223422

14. Prior Correspondence: NA

Design and Use of the Device:

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	√	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		√
Does the device contain components derived from a tissue or other biologic source?		√
Is the device provided sterile? (Handpiece)		√
Is the device provided sterile? (Tip)	√	
Is the device intended for single use? (Handpiece)		√
Is the device intended for single use? (Tip)	√	
Is the device a reprocessed single use device?		√
If yes, does this device type require reprocessed validation data?		√
Does the device contain a drug?		√
Does the device contain a biologic?		√
Does the device use software?		√

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Does the submission include clinical information?		√
Is the device implanted?		√

The Device User Fee has been forwarded for payment. A copy of the Device Fee User Payment Sheet can be found in Section 1 of this Premarket Notification. The User Fee payment identification number is: MD 6062646-956733

The Certification of Compliance, under 42 U.S.C. § 282 (j)(5)(B), with Requirements of Clinical Trials.gov Data Bank (42 U.S.C. § 282(j)), FDA Form 3674 follows this cover letter.

Two hardcopies of the Premarket Notification are provided. The information contained in this document is confidential and proprietary. Selected confidential and/or proprietary information needs to be deleted before this document is released through FOI Act requests.

If you have any questions regarding this submission, please contact me directly.

Dean E. Ciporkin

Senior Director, Regulatory Affairs and Quality Assurance

dciporkin@microlinesurgical.com

Phone: 978-867-1758

Fax: 978-922-9209

Please copy:

Bill McCallum

Regulatory Affairs Manager

bmccallum@microlinesurgical.com

Phone: 978-867-1726

Fax: 978-922-9209

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See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 10-31-2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Microline Surgical, Inc.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
July 13, 2012

3. ADDRESS *(Number, Street, State, and ZIP Code)*
800 Cummings Center, Suite 166T
Beverly, MA 01915

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 978 867 1726
(Fax) 978 867 1787

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

Common or usual name: Thermal Ligating Shears
Class II,

Proprietary Name: MiSeal Reposable Thermal Ligating Shears

Model Names and Numbers:	Model Number
MiSeal Reusable Handpiece 14cm	152-101R
MiSeal Reusable Handpiece 23cm	152-102R
MiSeal Reusable Handpiece 35cm	152-103R
MiSeal Reusable Handpiece 45cm	152-104R
MiSeal Thermal Ligating Shears Kit	452-131D

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) Wm. Shaw McCallum
(Title) Regulatory Affairs Manager

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
Microline Surgical, Inc.
800 Cummings Center, Suite 166T
Beverly, MA 01915

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 978 867 9810
(Fax) 978 867 1787

15. DATE OF CERTIFICATION
Jul 12, 2012

Form FDA 3674 (11/08) (FRONT)

PSC Graphics (301) 443-6090 EF

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4.

Indications For Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: MiSeal Reposable Thermal Ligating Shears

Indications for Use:

The MiSeal Reposable Thermal Ligating Shears are intended for the simultaneous cutting and cauterization of soft tissue during surgery, and cutting of natural or synthetic, nonmetallic sutures during surgery.

See Boilerplate

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Summary or Statement

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510(k) Summary

Submitted By: Microline Surgical

Contact Person: Dean Ciporkin

Date Prepared: July 13, 2012

Proprietary Name: MiSeal™ Reposable Thermal Ligating Shears

Classification Name: Electrosurgical Cutting and Coagulation Device and accessories
21 CFR § 878.4400
79 GEI

Predicate Device: This product is similar in design, composition, and function to the:
Starion Instruments Thermal Ligating Shears (K062257) cleared October 10, 2006

Device description and technological Characteristics:

The MiSeal Reposable Thermal Ligating Shears system consists of the following:

MiSeal Reusable Handpiece
MiSeal Thermal Ligating Shears Kit
Universal Power Supply 200-006R

The MiSeal Reposable Thermal Ligating Shears are designed to provide thermal ligation and division in various surgical procedures. The MiSeal Reposable Thermal Ligating Shears consist of a reusable handpiece with a disposable tip. The device has heating elements at the distal tip which are activated by a finger switch located on the handpiece of the device. The MiSeal Reposable Thermal Ligating Shears are designed to allow the surgeon control of the heating element power of the device in order to accommodate the individual patient anatomy. An instrument cord connects the handpiece to the dedicated Microline Surgical Universal Power Supply K070871.

The MiSeal Reposable Handpiece is supplied non-sterile in a foam cavity placed in a fiberboard carton and is for multiple patient uses following cleaning and steam sterilization procedures performed per the provided Instructions for Use. The handpiece can be used multiple times if cleaning and sterilization procedures are followed. The MiSeal Disposable Kit (the functional instrument Tip and power cable portion of the applied part of the system) is supplied sterile in a die-cut chipboard Packaging Insert and Tyvek/Mylar pouch and is labeled for single use only. The tip is intended to be used by a trained physician for a single patient use in open general surgery, open vascular surgery, and laparoscopic surgical procedures.

The MiSeal single use power cable is connected to the handle of the instrument handpiece and terminates at the electrical connection of the Universal Power Supply. The system power supply is supplied non-sterile for reusable use outside the sterile field.
The MiSeal device incorporates Hi and Low heating modes that are used to coagulate and cut soft tissue. The heating elements in the disposable tip are activated by a physician controlled finger switch located on the handpiece of the device. The MiSeal device is intended to provide general purpose dissection, spreading, and grasping of soft tissue during minimally invasive or open surgical procedures.

To seal and cut tissue, the physician grasps the desired tissue between the jaws of the MiSeal Reposable Thermal Ligating Shears and gently squeezes the thumb trigger and handpiece to close the jaws. Depressing the finger switch and squeezing the thumb trigger activates the heating elements in the distal tip. An audible low frequency tone accompanies the activation of the heating element in the variable mode to notify the physician the power is being applied. An audible high frequency tone will accompany the activation of the heating element in High power mode. Depressing the finger switch on the top of the handle provides either Hi or Low heating mode. Generally, a lower UPS output setting improves the sealing capabilities and lengthens the time required to divide tissue. Conversely, a higher output setting reduces the time to divide tissue and may result in decreased vessel seal integrity

Indications for Use:

The MiSeal Reposable Thermal Ligating Shears are intended for the simultaneous cutting and cauterization of soft tissue during surgery, and cutting of natural or synthetic, nonmetallic sutures during surgery.

Performance Testing:

Preclinical and performance tests were performed to assure the MiSeal Reposable Thermal Ligating Shears functioned as intended and met all product specifications. Sufficient data was generated and analyzed to prove that the MiSeal Reposable Thermal Ligating Shears was substantially equivalent to the predicate device.

Summary:
The information provided demonstrates that the MiSeal Reposable Thermal Ligating Shears is substantially equivalent to the Starion Instruments Thermal Ligating Shears in function, construction, intended use and indications for use.

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Truthful and Accuracy Statement

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See Re Revision

Premarket Notification Truthful And Accurate Statement

I certify the, in my capacity as the Regulatory Affairs Manager of Microline Surgical, Inc., 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.

Wm Shaw McCallum

Wm Shaw McCallum

July 13, 2012
(Date)

(Premarket Notification {510(k)] Number)

7

Class III Summary and Accuracy Statement

7. Class III Summary and Certification

This section is not applicable to the MiSeal Reposable Thermal Ligating Shears as it is a Class II Device per 21 CFR § 878.4400 Electrosurgical cutting and coagulation device and accessories.

8

Financial Certification of Disclosure Statement

8. Financial Certification of Disclosure Statement

This section is not applicable to the MiSeal Reposable Thermal Ligating Shears submission as no clinical studies have been conducted to support this 510(k) submission.

9

Declaration of Conformity and Summary Reports

9. Declaration of Conformity and Summary Reports

Not applicable, not an Abbreviated 510(k).

10

Executive Summary

10. Executive Summary

The MiSeal Reposable Thermal Ligating Shears is a hand-held surgical instrument and is indicated for the simultaneous cutting and cauterization of soft tissue during surgery and cutting of natural or synthetic, non-metallic sutures during surgery.

The term "Reposable" was developed by Microline Surgical and it was derived from using a reusable handpiece and a disposable tip.

The MiSeal Reposable Thermal Ligating Shears system consists of the following:

1. MiSeal Reposable (Reusable) handpieces consisting of 4 different shaft lengths, 14cm, 23cm, 35cm, and 45cm: supplied non-sterile for multiple uses.

2. MiSeal Reposable Thermal Ligating Shears Kit consisting of a 5mm curved jaw tip and instrument cord, supplied single patient use, sterile.

3. The Universal Power Supply (UPS) Model # 200-006R (K070871), a non-sterile reusable AC powered unit intended for use only with Microline Cautery and Thermal Ligating Shears Instruments.

> Note: MiSeal Reposable Thermal Ligating Shears and Universal Power Supply were developed by Starion Instruments Corp. Starion was acquired by Microline Surgical, Inc., on April 17, 2009 and was wholly owned by Microline in the spring of 1012. the predicate device, Thermal Ligating Shears K062257 was a Starion product at the time of the acquisition.

The predicate device for the MiSeal Reposable Thermal Ligating Shears is the Starion Instruments Thermal Ligating Shear, K062257, cleared on October 10, 2006. Starion Instruments named this device TLS3, model numbers 132-136D (35cm), 132-135D (23cm) and 132-134D (14cm).

Indications for Use:

From the Instructions for Use (predicate device); Thermal Ligating Shears; TLS3:
"For the simultaneous cutting and cauterization of soft tissue during surgery:
Cutting of natural or synthetic, non-metallic, sutures during surgery."

From the Instructions for Use for the subject of this submission:
"The MiSeal Reposable Thermal Ligating Shears are intended for the simultaneous cutting and cauterization of soft tissue during surgery, and cutting natural or synthetic, nonmetallic sutures during surgery."

11

Device Description

11. Device Description

The Thermal Ligating Shears (predicate device (TLS^3) K062257) are sterile, single use and are fully disposable. The subject of this submission is a reposable (reusable handpiece and disposable tip) version of the TLS^3, hereafter referred to as MiSeal Reposable Thermal Ligating Shears that fits the Microline Cost effective model of reposability. This includes a re-usable handpiece combined with a disposable tip.

The MiSeal Reposable Thermal Ligating Shears are intended to provide general-purpose dissection, spreading, and grasping of soft tissue during minimally invasive laparoscopic or open surgical procedures. The MiSeal also provides simultaneous sealing and cutting of soft tissue and vessels via a clinician-controlled finger switch.

The MiSeal incorporates a two-position finger button which activates the heated areas between the jaws of the device. The two-position finger button allows the user to activate the device in either the variable or the Hi modes of the Universal Power Supply. The variable mode is set to the desired power level for sealing and cutting and the Hi mode is used for fast cutting.

The two speed feature may also be utilized by the user in order to concentrate the majority of the task time on sealing (while in the variable mode) and then switch to the Hi mode in order to quickly cut. The MiSeal is powered by the Model # 200-006R Universal Power Supply.

Device Design Requirements:

The MiSeal is designed to be able to seal and cut tissue, ligaments and vessels. The MiSeal device is designed to have the same functional performance standards as the TLS^3 (predicate device). Competitive performance between the MiSeal and the TLS^3 is determined by comparing the devices' sealing ability when used on various vessels, burst strength and speed to perform a specific task, dissection capability, and thermal spread. The MiSeal is designed to be compatible with reusable and disposable 5mm trocar sheaths and cannulas and function during insufflation. The MiSeal is compatible with the 200-006R Universal Power Supply. The MiSeal reposable handpiece is designed for single handed operation of all functions as well as right and left hand operation. The MiSeal handpiece is designed to allow for cleaning and sterilization within a hospital environment.

Model Numbers:

Product Code	Description
152-101R	MiSeal Reusable Handpiece 14cm shaft
152-102R	MiSeal Reusable Handpiece 23cm shaft
152-103R	MiSeal Reusable Handpiece 35cm shaft
152-104R	MiSeal Reusable Handpiece 45cm shaft
452-131D	MiSeal Thermal Ligating Shears Kit

Table Illustrating the MiSeal and Thermal Ligating Shears (TLS3) Patient Contact Components and Materials

Patient Contact Components and Materials for MiSeal and Predicate Thermal Ligating Shears TLS3

Thermal Ligating Shears TLS3 Component Description	Material	Patient Contact?	MiSeal Component Description	Material	Patient Contact?
Low Resistance TLS3 Heater Assembly, Formed	(See below)	Y	Low Resistance TLS3 Heater Assembly, Formed	(See below)	Y
Nickel Wire, Cut, .013 x .125	(b)(4)	Y	Nickel Wire, Cut, .013 x .125	(b)(4)	Y
Copper Wire, 28HML, .820, Stripped .100 (Both Ends)		Y	Copper Wire, 28HML, .820, Stripped .100 (Both Ends)		Y
.018 Straight Heater, Drilled .070 (Both Ends), TLS3		Y	.018 Straight Heater, Drilled .070 (Both Ends), TLS3		Y
Polyimide Tubing, .015 ID, .125 Long		Y	Polyimide Tubing, .015 ID, .125 Long		Y
30 AWG Conductor		Y	30 AWG Conductor		Y
Silicone Primer, Clear, Unrestricted		Y	Silicone Primer, Clear, Unrestricted		Y
Silicone RTV, MasterSil 800		Y	Silicone RTV, MasterSil 800		Y
O-Ring		Y	O-Ring, Guide Rod, MiSeal		N
Bushing, O-Ring		Y	Support Ring		N
Bushing, Control Rod End		Y	Stub Tube Bushing		Y
Washer, Polyimide		Y	Washer, Polyimide		Y
Marker Band		Y	Marker Band		Y
TLS 35 Guide Tube Cover		Y	Heatshrink Tubing, MT-3000 3/16		N
TLS 35 Outer Tube, Uncoated		Y	Tube, Outer, 35C, MiSeal		Y
			Luer, Female		N
			Threaded Weld Ring		Y
			Tube, Weld, Outer, 35C		Y
			Tube, Stub, MiSeal		Y
			TLS 35 Outer Tube, Uncoated		Y
			Rod, Guide, 35C, MiSeal		Y
35 E-Brake, Slotted Feature Guide Rod		Y	Rod, Guide, Stub, MiSeal		Y
			Jaw, Lap, Left		Y
Jaw, Lap, Left		Y	Jaw, Lap, Right		Y
Jaw, Lap, Right		Y	Clevis, Insulative		Y
Clevis, Insulative		Y	Boot, Thick		Y
Boot, TLS3		Y	TLS3 Control Rod Bushing		Y
TLS3 Control Rod Bushing		Y	TLS3 Control Rod Rivet Link		Y
TLS3 Control Rod Rivet Link		Y	TLS3 Heat Spreader, Left, Type 19		Y
TLS3 Heat Spreader, Left, Type 19		Y	TLS3 Heat Spreader, Right, Type 19		Y
TLS3 Heat Spreader, Right, Type 19		Y	Rivet, Pivot, Semi-Tubular		Y
Rivet, Pivot, Semi-Tubular		Y	Link, Limiting, 30 Deg		Y
TLS3 Link, Stamped		Y	TLS3 Control Rod End, 0.025 Step		Y
TLS3 Control Rod End, 0.025 Step		Y	Clevis, Conductive, Stamped, Type 3		Y
Clevis, Conductive, Stamped, Type 3		Y			

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MiSeal Reposable Thermal Ligating Shears
Device Top Level Drawings

(b)(4)Engineering Drawing

(b)(4)Engineering Drawing

(b)(4)Engineering Drawing

(b)(4)Engineering Drawing

(b)(4)Engineering Drawing

12

Substantial Equivalence Discussion

12. Substantial Equivalence/Comparison Table

The Microline Surgical MiSeal Reposable Thermal Ligating Shears are substantially equivalent to the Starion Instruments TLS3 Thermal Ligating Shears, a legally marketed predicate device which has been granted market clearance on October 10, 2006 via 510(k) K062257. The modifications being incorporated (that differentiate from the predicate) include the following: A reusable handpiece, a single-use disposable tip, a rocker switch for tip installation, a flush port, and a single-use disposable cable.

The predicate TLS3 Thermal Ligating Shears are supplied sterile for single patient use. The Microline Surgical MiSeal Reposable Thermal Ligating Shears has a reusable handpiece, and a sterile single use tip that is threaded on the handpiece and disposed of after single patient use. Also included in the kit is a sterile single use electrical cable that connects the MiSeal to the Universal Power Supply (K070871).

The MiSeal Disposable Kit, consisting of one Disposable Tip and one Disposable Cable, is provided to the customer in a single-use, sterile, disposable pack. Tips and cables are intended to be assembled to the handle prior to use. The disposable pack is sterilized via a validated gamma irradiation process. The predicate device has the same tip and cable as the MiSeal, the only difference is the TLS3 tip and cable is permanently attached because the whole device is sold sterile, for single patent use. As stated above, the MiSeal Reposable Thermal Ligating Shears has a reusable handpiece, and a sterile single use tip that is threaded on the handpiece and disposed of after single patient use.

The similarities and differences are detailed in the table below:

Comparison Table

Characteristic	Starion Instruments Corporation TLS3 Thermal Ligating Shears 510(k) K062257 (Predicate device)	Microline Surgical Inc. MiSeal Reposable Thermal Ligating Shears
Indications for Use	For the simultaneous cutting and cauterization of soft tissue during surgery, and cutting of natural or synthetic, non-metallic sutures during surgery.	The MiSeal Reposable Thermal Ligating Shears are intended for the simultaneous cutting and cauterization of soft tissue during surgery, and cutting of natural or synthetic, nonmetallic sutures during surgery.
Target Population	Essentially all major surgical disciplines.	Same
Principle of Operation	Heat is conducted to tissue compressed within the jaws via heating elements in the instrument tip.	Same

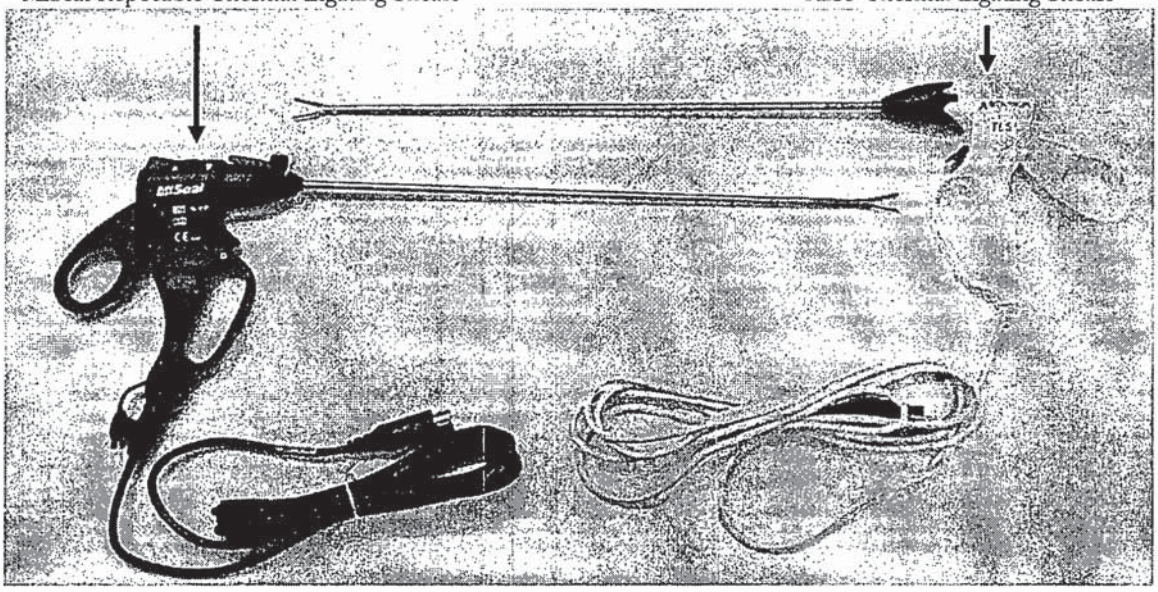
Energy Source	Electrical (D.C.) current from Starion Instruments Universal Power Supply (UPS)	Same, relabeled Microline Surgical
Method of Actuation	Finger switch	Same
Materials (patient contact)	Nickel alloy, nickel chromium, stainless steel, plated copper, coated copper, anodized aluminum, naphtha based primer, cyanoacrylate, nylon, polyimide, silicone, polyetherimide	Same
Performance	Meets IEC 60601-1 and IEC 60601-1-2 safety requirements	Same
Sterility	Gamma radiation, sterility assurance level (SAL) is 10^{-6}	Same for single use disposable tip and cable. Handle is autoclavable.
Cleaning and re-sterilization of the reusable hand piece	N/A Sterile for single use only.	Validated for cleaning and repeated sterilization procedures.
Primary Sterile Barrier	Tyvek/Mylar pouch	Same for single use disposable tip and cable.
Biocompatibility	All patient contact materials meet biocompatibility test per ISO 10993-1	Same
Mechanical Safety	Meets IEC 60601-1safety requirements	Same
Chemical Safety	Meets IEC 60601-1safety requirements	Same
Human Factors	Meets IEC 60601-1safety requirements	Same
Energy Used and/or Delivered	Maximum Output – 60W No Load Voltage – 9VDC	Same
Compatibility with Environment and other Devices	Meets IEC 60601-1 and IEC 60601-1-2 safety requirements	Same
Where Used	Hospital and surgery centers	Same
Standards Met	Meets IEC 60601-1 and IEC 60601-1-2 safety requirements	Same
Electrical Safety	IEC 60601-1safety requirements	Same
Thermal Safety	Meets IEC 60601-1safety requirements	Same
Radiation Safety	Meets IEC 60601-1-2 safety requirements	Same

Section 19 of this submission contains an animal study performed that evaluates the equivalency of the MiSeal Reposable Thermal Ligating Shears system and the TLS3 Thermal Ligating Shears. The Conclusion is: "The MiSeal device meets all the acceptance criteria of the test protocol as evidenced by the attached final report detailing acceptable test results. The MiSeal device is equivalent to the TLS3 as shown by in vivo and in vitro test results which supports the device equivalency between the MiSeal Reposable Thermal Ligating Shears the subject of this 510(k) submission, and the predicate TLS3 Thermal Ligating Shears.

Below is a photograph of the Thermal Ligating Shears TLS3 (predicate) and the MiSeal Reposable Thermal Ligating Shears, giving visual conformation of the similarities between the predicate and the subject of this submission and further supporting the equivalency of the predicate and subject of this submission.

MiSeal Reposable Thermal Ligating Shears

TLS3 Thermal Ligating Shears



The table below entitled "Patient Contacting Materials" shows that the patient contacting materials used to construct the Thermal Ligating Shears TLS3 (predicate) and the MiSeal Reposable Thermal Ligating Shears are exactly the same, demonstrating the equivalency of the predicate to the MiSeal.

Patient Contacting Materials

TLS3 Thermal Ligating Shears Materials, Patient Contact K062257	MiSeal Reposable Thermal Ligating Shears Materials, Patient Contact
(b)(4)	

Summary Description

Side-by-Side Performance Specification Comparison of the Predicate TLS3 with MiSeal

The attached table provides a comparison of the significant physical and performance characteristics of the device, such as device design, material used, and physical properties of the predicate device TLS3 with the MiSeal Thermal Ligating Shears.

Each device was reviewed for satisfying the criteria provided in each section of the original TLS3 product specification, shown in the first column, 'PS0023 Section' as related to the parameters noted in the second column, 'Component, Characteristic, or Requirement Description'.

The sections of the product specification are organized by row in the table, and the results of each device's conformance to the specific requirements of each section are organized in the columns, 'Result for TLS3', for the Thermal Ligating Shears, and 'Result for MiSeal', for the MiSeal Thermal Ligating Shears.

A column, 'Result is Equivalent?' is provided to indicate whether the MiSeal is equivalent to the particular section of the TLS3 Product Specification with an entry of 'Y', or if it is not equivalent, with an entry of 'N'.

If the MiSeal is equivalent, an entry of 'N/A' is noted in the 'State Reason for Variance' column. If the MiSeal is not equivalent, a description of the condition of the MiSeal which contrasts the TLS3 requirement is noted in the final column of the table, 'State Reason for Variance', either stating the origin of the differentiating characteristic derived from the MiSeal product specification (PS0027), or with further information provided by a descriptive statement.

Conclusion

The MiSeal Thermal Ligating Shears is equivalent to the predicate TLS3 Thermal Ligating Shears. The variances between the product specifications resulted from the differences in the designs between the fully disposable TLS3, and the MiSeal which consists of a reusable handle, and a disposable tip with disposable cable.

Side By Side Performance Specification Comparison
Predicate TLS3/MiSeal

PS0023 Section	Component, Characteristic or Requirement Description	Result for TLS3 K062257	TLS3 Reference Specification	Result for MiSeal (Subject of this Submission)	MiSeal Reference Specification	Result is Equivalent?	State Reason for Variance
5.1	(b)(4)						
5.2							
5.3							
5.4							
5.5							
5.6							
5.7							
5.8							
5.9							
5.10							
5.11							
5.12							

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Side By Side Performance Specification Comparison
Predicate TLS3/MiSeal

PS0023 Section	Component, Characteristic or Requirement Description	Result for TLS3 K062257	TLS3 Reference Specification	Result for MiSeal (Subject of this Submission)	MiSeal Reference Specification	Result is Equivalent?	State Reason for Variance
5.13						Y	N/A
5.14							
5.15							
5.16							
5.17							
5.18							
5.19							
5.20							
5.21							
5.22							
5.23							

(b)(4)

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Side By Side Performance Specification Comparison
Predicate TLS3/MiSeal

PS0023 Section	Component, Characteristic or Requirement Description	Result for TLS3 K062257	TLS3 Reference Specification	Result for MiSeal (Subject of this Submission)	MiSeal Reference Specification	Result is Equivalent?	State Reason for Variance
5.24	[redacted]					Y	N/A
5.25							
5.26							
5.27							
5.28							
5.29							
5.30							
5.31							
5.32							
5.33							
5.34							

(b)(4)

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Side By Side Performance Specification Comparison
Predicate TLS3/MiSeal

PS0023 Section	Component, Characteristic or Requirement Description	Result for TLS3 K062257	TLS3 Reference Specification	Result for MiSeal (Subject of this Submission)	MiSeal Reference Specification	Result is Equivalent?	State Reason for Variance
5.35						N	(b)(4)
5.36							
5.37							
5.38							
5.39							
5.40							
5.41							

(b)(4)

Side By Side Performance Specification Comparison

Predicate TLS3/MiSeal

PS0023 Section	Component, Characteristic or Requirement Description	Result for TLS3 K062257	TLS3 Reference Specification	Result for MiSeal (Subject of this Submission)	MiSeal Reference Specification	Result is Equivalent?	State Reason for Variance
5.42	(b)(4)						
5.43							
5.44							
5.45							
5.46							
5.47							
5.48							

Side By Side Performance Specification Comparison

Predicate TLS3/MiSeal

PS0023 Section	Component, Characteristic or Requirement Description	Result for TLS3 K062257	TLS3 Reference Specification	Result for MiSeal (Subject of this Submission)	MiSeal Reference Specification	Result is Equivalent?	State Reason for Variance
5.49							
5.50							
5.51							
5.52							
5.53							
5.54							
5.55							
5.56							

(b)(4)

Side by Side Performance Specification Comparison

Predicate TLS3/MiSeal

PS0023 Section	Component, Characteristic or Requirement Description	Result for TLS3 K062257	TLS3 Reference Specification	Result for MiSeal (Subject of this Submission)	MiSeal Reference Specification	Result is Equivalent?	State Reason for Variance
5.57							
5.58							
5.59							
5.60							
5.61							
5.62							
5.63							

(b)(4)

000058

Side By Side Performance Specification Comparison

Predicate TLS3/MiSeal

PS0023 Section	Component, Characteristic or Requirement Description	Result for TLS3 K062257	TLS3 Reference Specification	Result for MiSeal (Subject of this Submission)	MiSeal Reference Specification	Result is Equivalent?	State Reason for Variance
5.64	(b)(4)						
5.65							
7.1							
8.1							
8.2							

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Side By Side Performance Verification Comparison
Predicate TLS3/MiSeal

PS0023 Section	Component, Characteristic or Requirement Description	Result for TLS3 K062257	TLS3 Reference Specification	Result for MiSeal (Subject of this Submission)	MiSeal Reference Specification	Result is Equivalent?	State Reason for Variance
8.3	(b)(4)						
8.4							
9.1							
10.1							

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Summary

Substantial equivalence is supported by the table comparing the similarities and differences, by the animal study that was performed that evaluated the simulated use by comparing the performance of both the MiSeal Reposable Thermal Ligating Shears system and the TLS3 Thermal Ligating Shears.

MiSeal and TLS3 physical characteristic similarities as seen in the comparison photograph above further exemplify the substantial equivalence of the predicate and the subject of this submission, the MiSeal Reposable Thermal Ligating Shears.

The same patient contacting materials are used in both the MiSeal Reposable Thermal Ligating Shears system and the TLS3 Thermal Ligating Shears, another characteristic supporting the claim of substantial equivalence.

The Side-by-Side Performance Specification Comparison of the Predicate TLS3 with MiSeal table further corroborates the substantial equivalence claim.

Microline Surgical is confident that the evidence presented in this section of the submission successfully demonstrates the substantial equivalence of the MiSeal Reposable Thermal Ligating Shears system and the TLS3 Thermal Ligating Shears.

13

Proposed Labeling

13 Labeling

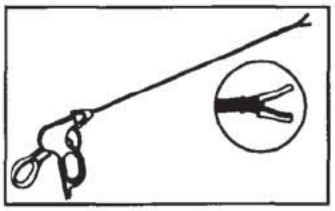
In this section of the submission, Labeling for the predicated device (Thermal Ligating Shears, TLS3 is provided. Labeling for the MiSeal Reposable Thermal Ligating Shears (Handpiece and Tip Kit) is also supplied. Lastly, the labeling for the Universal Power Supply model number 200-006R is provided.

Predicate TLS^3 Labeling

MICROLINE
SURGICAL

Microline Surgical, Inc.
800 Cummings Center, Suite 166T
800 Cummings Center, Suite 157X
Beverly, MA 01915 U.S.A.

TLS^3
Thermal Ligating Shears
Curved Jaw



STERILE R

☐ REF 132-134D
14C (14 cm)

☐ REF 132-135D
23C (23 cm)

☐ REF 132-136D
35C (35 cm)

LOT

Contents: One (1) sterile unit in unbroken, undamaged package. For use with Universal Power Supply. Manufactured under one or more of US patents: 7,033,351; 7,011,656; 6,908,463; 6,650,880; 6,695,837; 6,626,901. Patents Pending. All Rights Reserved

Inhalt: Eine (1) Einheit, steril bei ungeöffneter, unbeschädigter Verpackung. Zur Verwendung mit Universal-Stromversorgung. Patente angemeldet.

Contenido: Una (1) unidad estéril en envase no roto ni dañado. Para uso con la fuente de alimentación universal. Patentes solicitadas.

Contenu : Une (1) unité stérile sous conditionnement intact, non ouvert. À utiliser avec le bloc d'alimentation universelle. Brevets en instance.

Contenuto: una (1) unità sterile in confezione chiusa e integra. Per l'uso con l'alimentatore universale. Brevetti in corso di registrazione.

Inhoud: Eén (1) steriele eenheid in niet-aangebroken, onbeschadigde verpakking. Voor gebruik met de universele stroombron. Octrooien aangevraagd.

Conteúdo: Uma (1) unidade estéril numa embalagem intacta, não danificada. Para utilizar com a Unidade de Alimentação Universal. Patentes pendentes.

İçerik. Aşılmamış ve hasar görmemiş paket içinde bir adet (1) steril ünite. Evrensel Güç Kaynağı ile kullanım içindir. Patentler Bekleniyor.

CE 0120 Rx Only LBL0102 Rev H

MICROLINE SURGICAL
☐ REF 132-134D 14C (14 cm) ☐ REF 132-135D 23C (23 cm) ☐ REF 132-136D 35C (35 cm)
TLS^3
Thermal Ligating Shears - Curved Jaw

(b) (6)

1/18/2012

THIS LINE IS EXACTLY 5 INCHES LONG. USE FILM POSITIVE FOR ARTWORK ONLY.

PAPER REPRODUCTIONS ARE NOT TO BE USED AS ARTWORK.

NOTES:
1. OVERALL SIZE OF LABEL IS 5.25" x 10.5"
2. UNLESS OTHERWISE SPECIFIED ALL DIMENSIONS ARE +/-.05
3. COLORS: PMS 431 (grey), PMS 325 (blue) AND BLACK
4. MATERIAL: WHITE, TRANSFER PREMIUM WHITE, MATTE COATED, LIGNIN FREE PAPER
5. ADHESIVE: RP51 (UPM RAFLATAC), MODIFIED ACRYLIC DISPERSION, PERMANENT
6. GAP: 0.125"
7. MAGENTA LINE DOES NOT PRINT

REVISIONS:
G - ECO 2124: CHANGED FINISHED SIZE FROM 5" X 10.25" TO 5.25" X 10.5" AND ADD GAP MEASUREMENT
H - ECO 2779: CONVERSION FROM STARION TO MICROLINE

MICROLINE SURGICAL

Microline Surgical, Inc.
800 Cummings Center, Suite 166T
800 Cummings Center, Suite 157X
Beverly, MA 01915 U.S.A.

TITLE: **POUCH AND BOX LABEL**
TLS3 Thermal Ligating Shears - Curved Jaw

(b) (6)

DATE: 12/22/11
1.19.12

APPRVD:

MAT'L: SEE NOTES

SIZE: B | DWG No: LBL0102 | REV: H

SCALE: 70% | SHT 1 OF 1

000065

MICROLINE SURGICAL

ENGLISH

Microline Surgical, Inc.
800 Cummings Center, Suite 166T
800 Cummings Center, Suite 157X
Beverly, MA 01915 U.S.A.
TEL: (978) 922-9810

TLS^3 - Thermal Ligating Shears - Instructions For Use Only for use with:
Microline UPS (Universal Power Supply) (200-006R)

Device Description
The Microline TLS3 Thermal Ligating Shears are designed to provide thermal ligation and division in various endoscopic procedures. The TLS3 has two heating elements at the distal tip which are activated by a finger switch located on the hand piece of the device. The device is designed to allow the surgeon to vary the heating element power in order to accommodate individual patient anatomy. A power cord extends from the hand piece of the device and connects to the UPS (Universal Power Supply).

Note: See Instructions for Use for the Universal Power Supply.

Intended Use
The device is a single use device and is intended to be used once only for a single patient. The device is intended for simultaneous cutting and cauterization of soft tissue during surgery. The device may also be used for cutting natural or synthetic, non-metallic sutures during surgery.

Connection to Power Source:
1. Remove the device from packaging. Do not attempt to remove the tip boot.
2. Uncoil the device's power cord; pass the connector end of the power cord off the sterile field.
3 Align the key portion of the connector with the key portion of the instrument connector receptacle on the UPS. Insert the device connector firmly into the instrument connector receptacle (non-sterile) of the UPS.
4. Turn on UPS power switch.

Note: A light adjacent to the instrument connector receptacle of the UPS will illuminate to verify proper alignment of the connectors. If *the light is not illuminated after turning ON the UPS, unplug the device connector and realign the key portion and reinsert into the* instrument receptacle.

Note: The heating element output can be adjusted in the "Variable" mode if desired. (See the UPS Instructions for Use)

Note: The heating element spans the length of the white sleeve. Tissue grasped outside this region will not be subject to sealing and division by the device

Pre-Check:
The TLS3 has two power options accessible from the finger switch of the hand piece, a variable mode (manually set at the UPS) and a high mode. The following sequence will verify electrical functions: (Caution: Do not touch the device tips while performing the pre-check as this may cause injury.)
1 Adjust the knob setting to #1 on the UPS to activate the heat output to minimum power (See the UPS Instructions for Use).
2. Soak a sterile 4x4 gauze pad in saline.
3. Place the gauze pad between the jaws of the device and close the jaws using the thumb trigger.
4 There should be no steam generated from the gauze pad nor tones emitted from the UPS when the jaws are closed but the finger witch is not depressed

TLS3 Variable Power Check
5. Depress the finger switch partially. This allows the user to adjust the heat output (via the power supply). A hissing sound from the gauze pad and a pulsing tone indicates the device is active in the "Variable" mode of the UPS. If a constant tone is emitted and steam generated, the finger switch was depressed too far. Release the finger switch and try again.

TLS3 High Power Check
6. Continue to depress the finger switch until it is fully depressed. This engages the high power option in thedevice activating the heat output to maximum power. Generation of steam with a hissing sound from the gauze pad and a continuous higher pitched tone indicate the device is active in the "High" mode of the UPS. This mode is utilized in avascular tissue or where sealing of vessels is not a primary *concern.*

Troubleshooting
- If there is no audible tone: Check the electrical connections and ensure the power switch is in the "ON" position. An indicator light located at the receptacle of the UPS for the device should be illuminated, in addition to the power indicator light on the UPS.
- Generation of steam during variable power check: Verify power supply setting of #1.
- Absence of steam during high power check: Add more saline to the gauze pad.
- If there is hissing sound and/or steam generation with no audible tone: DO NOT use the device or power supply and contact Microline Customer Service

Using the Device
***Note**: Individual patient anatomy and physician technique can influence the performance of the device. The following steps are* recommendations only.
1 Grasp desired tissue between the jaws of the device and gently squeeze the thumb trigger and handle to close the jaws. Depress the finger switch to achieve the desired power output. Do not squeeze the handle with excessive force. Hemostasis is best achieved with gentle pressure. Generally, lower heat ranges increase the sealing capabilities and the time required to divide tissue. Higher heat ranges decrease the time to divide and may compromise seal integrity.

Note. Depressing the finger switch activates the heating elements. This is not recommended when the jaws are open or no tissue is *present between the jaws of the device.*
2 After the desired sealing and division of tissue is accomplished, release the finger switch and open the jaws. This deactivates the heating elements.

Note: After removing the device, examine tissue for hemostasis. If hemostasis is not present, use appropriate techniques to achieve hemostasis.
3. If desired, progress to a new region of tissue to be sealed and divided.

Note: *It may be desirable to occasionally clean the tip of the device during the surgical procedure.* A saline-moistened surgical gauze or sponge may be applied gently to the jaws to remove buildup of coagulated blood and tissue debris by cleaning in a linear motion along the heating elements. After cleaning the tip, it may also be desirable to open and close the jaws several times by squeezing and releasing the handle to ensure optimal performance.
4. At the end of the surgical procedure, disconnect and discard the device.

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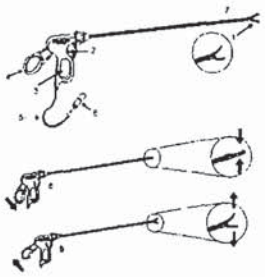
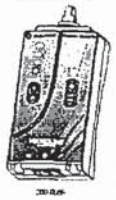
Thermal Ligating Shears
(Sterile)

1- Jaws and heating element(s)
2- Finger switch
3- Handle
4- *Thumb Trigger*
5- Power Cord
6- Connector
7- Tip Cleaning Direction
8- Squeeze thumb trigger and handle to close jaws
9- Release thumb trigger and handle To open jaws



Universal Power Supply
(non sterile)



Label graphics may vary

Precautions And Warnings

- Device is not designed for reuse or reuse decontamination processes. Reuse of single-use devices creates a potential risk of patient or user infections, injury, illness or death.
- Do not use if instrument or cord is damaged.
- Do not use a scalpel or other sharp metal instrument to clean the device. Do not grasp the tip boot and heater during cleaning as doing so may damage the tip and could prevent the device from functioning properly. Wipe only.
- Refrain from unnecessary activation of the heating elements while there is no tissue grasped between the jaws of the device as this activity may result in premature degradation of the device
- Do not immerse the device's handle in liquids.
- Do not touch an electrosurgical (Bovie) electrode to any part of the device.
- Use the device only with the UPS (Universal Power Supply). Use of any other power supply may damage the device and could prevent proper function during use.
- Device is not intended for continuous use. A typical duty cycle of approximately five (5) to ten (10) seconds on, ten (10) seconds off is recommended.
- Activating the device with excessive force or traction may result in an incomplete seal. If hemostasis is not present, use appropriate techniques to achieve hemostasis
- Procedures using instruments for sealing and dividing of tissue during surgery should be performed only by persons having adequate training and familiarity with these surgical techniques. Consult the medical literature relative to techniques, complications and hazards prior to performance of any procedure. Surgeons using this device should be *familiar with the specific anatomy of the region in which they intend to perform the procedure.*
- There are no unusual risks associated with the proper disposal of this equipment. Follow any local regulations regarding proper disposal of used surgical equipment.
- Store in a cool, dry place.

Warning:
Do not use in the presence of flammable materials (e.g. alcohol, flammable anesthetics).
Always disconnect the instrument before discarding, the UPS power supply is reusable.

Contraindications
TLS3 is not to be used as a fallopian tube sterilization device.

Compliance with Standards
When used with the UPS, device complies with IEC60601-1 requirements for type CF applied part and meets electromagnetic compatibility requirements of IEC60601-1-2.

Symbol Definition

 Means: Variable Power.

 Means: High Power.

 Means: Does not contain latex.

EC REP **Medical Device Safety Service GmbH**
Schiffgraben 41
D-30175 Hannover
Germany

CE 0120

Rx Only

IFU0033 Rev F

Manufactured under one or more of US patents: 7,033,351; 6,908,463; 6,860,880, 6,695,837; 6,626,901. *Patents Pending* All Rights Reserved.

MiSeal Labeling

MICROLINE™
SURGICAL

MiSeal Reusable Handpiece

REF
☐ 152-101R 14C (14 cm)
☐ 152-102R 23C (23 cm)
☐ 152-103R 35C (35 cm)
☐ 152-104R 45C (45 cm)

09-38-00323-00 Rev A

REF
☐ 152-101R 14C (14 cm)
☐ 152-102R 23C (23 cm)
☐ 152-103R 35C (35 cm)
☐ 152-104R 45C (45 cm)

LOT

SN

MiSeal Reusable Handpiece

Contents: One (1) non sterile, reusable handpiece in unbroken, undamaged package. For use with Universal Power Supply (UPS) and tip kit. Manufactured under one or more of US patents: 7,033,351; 7,011,656; 6,908,463; 6,860,880; 6,695,837; 6,626,901. Patents Pending. All Rights Reserved.
Inhalt: Ein (1) nicht-steries wiederverwendbares Handstück in unzerstörter, unversehrter Packung. Zur Verwendung mit dem Universal-Netzgerät und dem Spitzen-Kit. Hergestellt unter einem oder mehreren der US-Patente: 7,033,351; 7,011,656; 6,908,463; 6,860,880; 6,695,837; 6,626,901. Patente angemeldet. Alle Rechte vorbehalten.
Contenido: Una (1) pieza de mano no estéril y reutilizable en empaque intacto y no dañado. Para utilizarse con el Adaptador de corriente de (UPS) y el Kit de punta de . Fabricado bajo una o más patentes estadounidenses: 7,033,351; 7,011,656; 6,908,463; 6,860,880; 6,695,837; 6,626,901. Patentes en trámite. Reservados todos los derechos.
Contenu : Une (1) poignée réutilisable non stérile sous emballage scellé intact. À utiliser avec le bloc d'alimentation universel Universal Power Supply (UPS) et le kit d'embout . Fabriqué sous l'un des brevets américains suivants : 7,033,351; 7,011,656; 6,908,463; 6,860,880; 6,695,837; 6,626,901. Brevets en cours. Tous droits réservés.
Contenuto: Un: (1) manipolo riutilizzabile non sterile in confezione intatta, integra. Da usarsi con l'alimentatore universale (UPS) e il kit di punta. Prodotto sotto uno o più dei seguenti brevetti statunitensi: 7,033,351; 7,011,656; 6,908,463; 6,860,880; 6,695,837; 6,626,901. Brevetti in fase di registrazione. Tutti i diritti riservati.

MICROLINE
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Contém: Uma (1) peça de mão reutilizável, não esterilizada, em embalagem intacta, sem danos. Para utilização com a fonte de alimentação universal (UPS) e kit de ponta da . Manufactura sob uma ou mais patentes dos E.U.A.: 7,033,351; 7,011,656; 6,908,463; 6,860,880; 6,695,837; 6,626,901. Patentes pendendo. Todos os direitos reservados.
İçindekiler: Bir (1) adet kirilmamış, hasarsız ambalaj içinde, steril olmayan, yeniden kullanılabilir el ünitesi. Universal Güç Kaynağı (ÜGK) ve Uç Takımı ile kullanılmak içindir. 7,033,351; 7,011,656; 6,908,463; 6,860,880; 6,695,837; 6,626,901 numaralı ABD patentlerinin biri veya daha fazlası altında üretilmiştir. Patentler İşlem Sürecindedir. Tüm Hakları Saklıdır.

Rx Only
Autoclavable

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09-38-00322-00 Rev A

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MICR LINE
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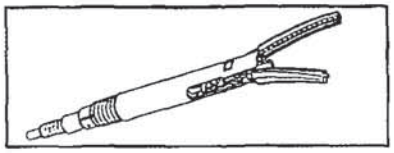
MiSeal Thermal Ligating Shears Kit

5 mm Curved Jaw Tip and Instrument Cord



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REF 452-131D

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Contents: One (1) sterile unit in unbroken, undamaged package. *For use with Universal Power Supply. Manufactured* under one or more of US patents: 7,033,351; 6,908,463; 6,860,880; 6,695,837; 6,626,901. Patents Pending. All Rights Reserved.

Inhalt: Eine (1) Einheit, steril bei ungeöffneter, unbeschädigter Verpackung. Zur Verwendung mit Universal-Stromversorgung. Patente angemeldet.

Contenido: Una (1) unidad estéril en envase no roto ni dañado. Para uso con la fuente de alimentación universal. Patentes solicitadas.

Contenu : Une (1) unité stérile sous conditionnement intact, non ouvert. À utiliser avec le bloc d'alimentation universelle. Brevets en instance.

Contenuto: una (1) unità sterile in confezione chiusa e integra. Per l'uso con l'alimentatore universale. Brevetti in corso di registrazione.

Inhoud: Eén (1) steriele eenheid in niet-aangebroken, onbeschadigde verpakking. Voor gebruik met de universele stroombron. Octrooien aangevraagd.

Conteúdo: Uma (1) unidade estéril numa embalagem intacta, *não danificada. Para utilizar com a Unidade de Alimentação* Universal. Patentes pendentes.

İçerik: Açılmamış ve hasar görmemiş paket içinde bir adet (1) steril ünite. Evrensel Güç Kaynağı ile kullanım içindir. Patentler Beklenlyor.

EC REP **Medical Device Safety Service GmbH**
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D-30175 Hannover
Germany

CE 0120 **Rx Only** LBL0121 Rev E

MICR LINE SURGICAL MiSeal Thermal Ligating Shears Kit
5 mm Curved Jaw Tip and Instrument Cord
REF 452-131D

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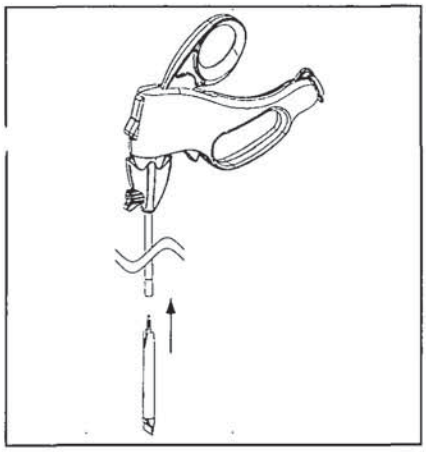

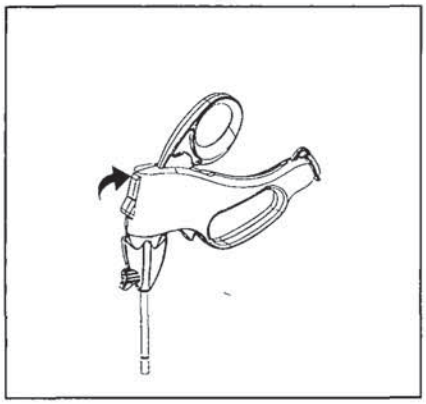

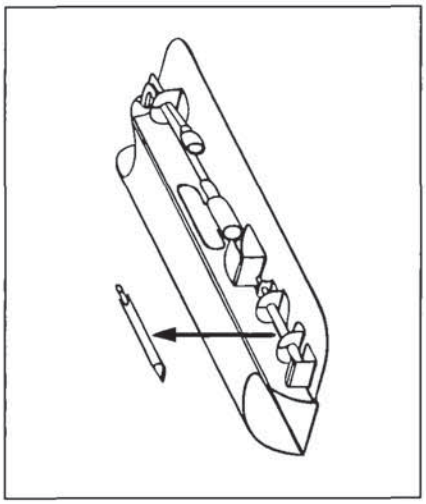

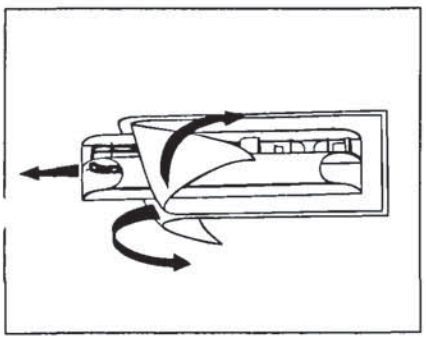

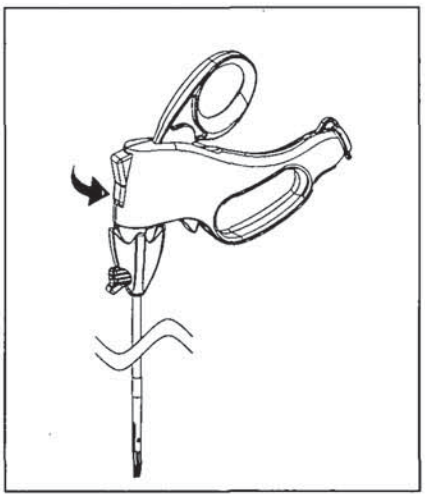

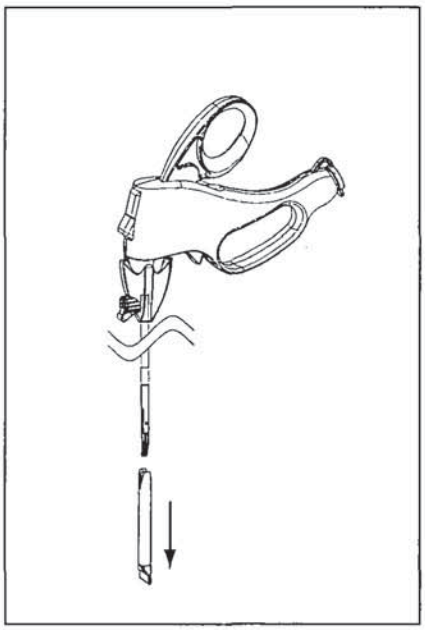

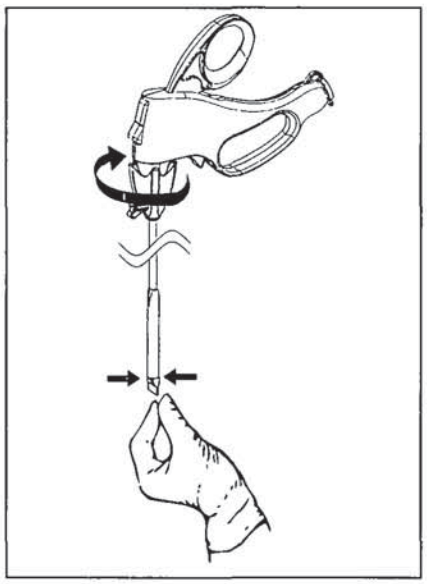

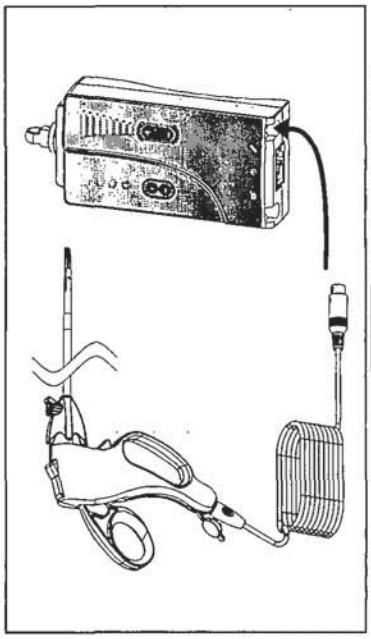

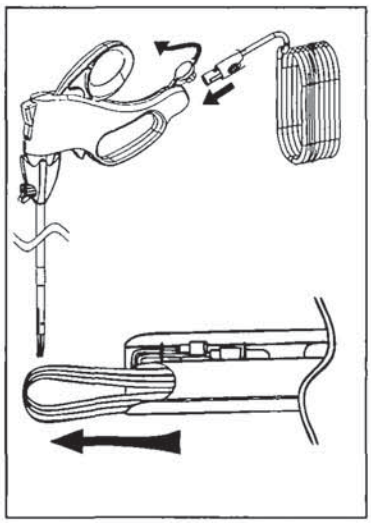

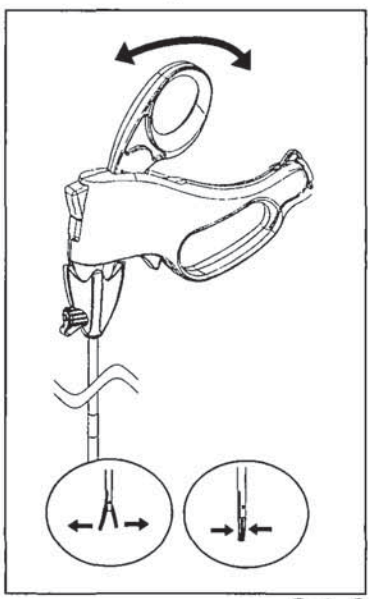

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EC REP

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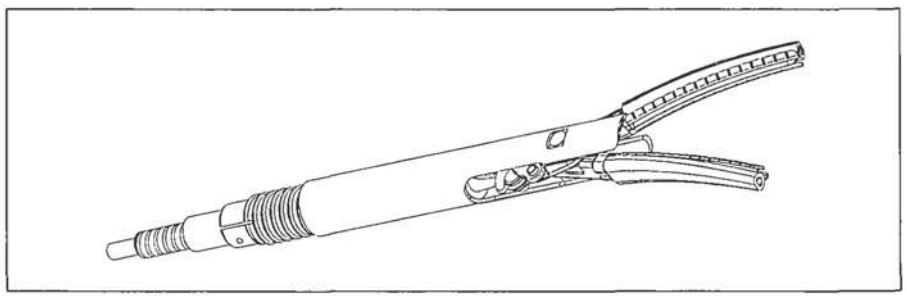
MICROLINE
SURGICAL

MiSeal Kit

5mm Curved Jaw Tip and Instrument Cord



REF 452-131D

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MiS ™ Reposable Thermal Ligating Shears

I ons For Use

C. .se with Microline Surgical Universal Power Supply (UPS) (REF 200-006R). Please see Instructions for Use packaged with the MiSeal Kit and the UPS.

Device Description

The Microline Surgical MiSeal Reposable Thermal Ligating Shears are designed to provide thermal ligation and division in various surgical procedures The MiSeal Reposable Thermal Ligating Shears consist of a reusable handpiece with a disposable tip. The device has heating elements at the distal tip which are activated by a finger switch located on the handpiece of the device. The MiSeal Reposable Thermal Ligating Shears are designed to allow the surgeon control of the heating element power of the device in order to accommodate for individual patient anatomy. An instrument cord connects the handpiece to the Universal Power Supply (UPS)

Intended Use

The MiSeal Reposable Thermal Ligating Shears are intended for the simultaneous cutting and cauterization of soft tissue during surgery, and cutting natural or synthetic, nonmetallic sutures during surgery. The MiSeal Kit contains a disposable tip and an instrument cord, which are single patient use. The MiSeal Handpiece can be used multiple times when the cleaning and sterilization procedures detailed in this Instructions For Use are followed

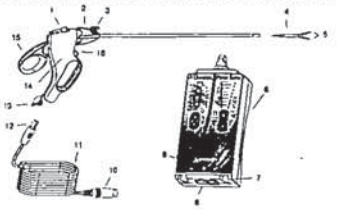

Figure 1

1. Rocker Button
2. Rotator
3. Luer Cap
4. Disposable Tip
5. Jaws with Heating Elements
6. Universal Power Supply (UPS)
7. Instrument Connector Receptacle
8. On/Off Switch
9. Power On LED Indicator
10. UPS Connector
11. Disposable Instrument Cord
12. Handpiece Connector
13. Receptacle Cap
14. Reusable Handpiece
15. Thumb Trigger
16. Finger Switch

Handpiece / Tip Assembly:

1. Remove the MiSeal Disposable Tip from the outer packaging. Keep the tip within the clear tubing as this will help the tip's jaws remain closed during tip installation.
2. Push the rocker button on the rear of the handpiece to the "load" position to engage the shaft locking mechanism (See Figure 2) A red graphic indicator will now be visible on the side of the rocker button.

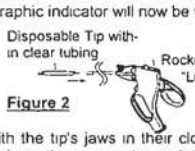

Figure 2

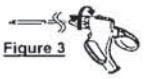

Figure 3

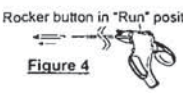

Figure 4

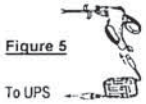

Figure 5

3 With the tip's jaws in their closed position, insert the tip into shaft. If the jaws are not completely closed when screwed onto the handpiece, they may not completely close to cut or grasp.
4. Holding the metallic tube of the tip within the clear tubing, turn the rotator clockwise until the tip is screwed tight and clicks into place (See Figure 3). Ensure that the rear hub of tip is in full contact with the shaft of the handpiece such that no gap exists between the rear hub of the tip and the end of the shaft
5. Remove the clear tubing
6. Push the rocker button on the handpiece forward to the "run" position to disengage the shaft locking mechanism (See Figure 4). A g aphic indicator will now be visible on the side of the rocker button
7 .e device by moving the thumb trigger to verify proper jaw opening and closing.
8. The device is ready to connect to the UPS for pre-check.

Connection to Power Source (See Figure 5)

1 Remove the MiSeal Disposable Instrument Cord from the packaging.
2 Unplug the receptacle cap from the handpiece.
3. Uncoil the instrument cord; align the key portion of the handpiece connector with the key portion of the connector receptacle on the MiSeal Handpiece Insert the handpiece connector firmly into the connector receptacle of the MiSeal Handpiece.
4. Pass the UPS connector end of the MiSeal Instrument Cord off the stenle field.
5. Align the key portion of the UPS connector with the key portion of the instrument connector receptacle on the UPS. Insert the UPS connector firmly into the instrument connector receptacle (non-sterile) of the UPS.
6 Turn on the UPS power switch.

Notes:

-A light adjacent to the instrument connector receptacle of the UPS will illuminate to verify proper connection If the light is not illuminated after turning "ON "the UPS, unplug the UPS connector, realign the key portion and reinsert the connector into the instrument receptacle.
-The heating elements' power can be adjusted in the "Variable" mode if desired (See the UPS Instructions for Use)
-The heating elements span the length of the jaws. Tissue grasped outside this region will not be subject to sealing and division

Pre-Check

The MiSeal Reposable Thermal Ligating Shears have two power options accessible from the finger switch of the handpiece, a variable mode (power output manually set at the UPS) and a high mode. Do not touch the device tip while performing the pre-check as this may cause injury. The following sequence will verify electrical function:

1. Press the buttons on the UPS to adjust the power output setting to #1 to reduce the heat output to minimum power (See the UPS Instructions for Use).
2 Soak a sterile 4 inch x 4 inch gauze pad in saline.
3. Place the gauze pad between the jaws of the device and close the jaws using the thumb trigger (See Figure 6) Do not depress the finger switch.
4. There should be no steam generated from the gauze pad nor tones emitted from the UPS

Variable Power Check

5 Depress the finger switch partially This allows the user to adjust the heat output (via the UPS). A hissing sound from the gauze pad and a pulsing tone indicate the device is active in the "Variable" mode of the UPS. If a constant tone is emitted and steam generated, the finger switch was depressed too far Release the finger switch and try again. This mode is utilized when vessels are being sealed.

High Power Check

6. Continue to depress the finger switch until it is fully depressed. This engages the high power option in the device activating the heat output to maximum power. Generation of steam with a hissing sound from the gauze pad and a continuous higher pitched tone indicate the device is active in the "High" mode of the UPS. This mode is utilized in avascular tissue or where sealing of vessels is not a primary concern.

Troubleshooting

- If there is no audible tone, check the electrical connections to the UPS and ensure the power switch is in the "ON" position. An indicator light located at the instrument connector receptacle of the UPS should be illuminated, in addition to the green power indicator light on the UPS
- If steam is generated during variable power check, verify a #1 UPS setting.
- If there is an absence of steam during high power check, add more saline to the gauze pad.
- If there is hissing sound and/or steam generation without an audible tone, DO NOT use the device or UPS and contact Microline S ' Customer Service

Using the Device

N. ndividual patient anatomy and physician technique can influence the performance of the device The following steps are recommendations only.

1. Grasp desired tissue between the jaws of the MiSeal Reposable Thermal Ligating Shears and gently squeeze the thumb trigger and handpiece to close the jaws (See Figure 6). Depress the finger switch to achieve the desired power output Do not squeeze the handpiece with excessive force. Hemostasis is best achieved with moderate pressure. Generally, lower heat ranges increase the sealing capabilities and the time required to divide tissue. Higher heat ranges decrease the time to divide and may compromise seal integrity

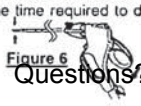

Figure 6

Figure 7

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Note: Depressing the finger switch and squeezing the thumb trigger activates the heating elements. This is not recommended when there is no tissue between the jaws of the MiSeal Reposable Thermal Ligating Shears.
2. After the desired sealing and dividing of tissue has been achieved, release the finger switch and thumb trigger which deactivates the heating elements.
3. After removing the device, examine tissue for hemostasis. If hemostasis is not present, use appropriate techniques to achieve hemostasis.
4. If desired, progress to a new region of tissue to be sealed and divided.
Note: It may be desirable to occasionally clean the tip of the device during the surgical procedure. A saline-moistened surgical gauze or sponge may be applied gently to the jaws in a linear motion along the heating elements to remove buildup of coagulated blood and tissue debris. After cleaning the tip, it may also be desirable to open and close the jaws several times by squeezing and releasing the thumb trigger to ensure optimal performance.
5. At the end of the surgical procedure, disconnect and discard the MiSeal Tip and Instrument Cord. To remove the instrument cord, hold the handpiece connector and pull away from the handpiece. To remove the tip, hold the rotator and turn the tip counter-clockwise until detachment is achieved.

Precautions and Warnings

- The MiSeal Tip and Instrument Cord are not designed for reuse or reprocessing for reuse. Reuse of single-use devices creates a potential risk of patient or user infections, injury, illness or death.
- Do not use if the handpiece, tip or instrument cord is damaged.
- Do not use a scalpel or other sharp metal instrument to clean the tip's jaws as the heating elements may be damaged.
- Refrain from unnecessary activation of the heating elements while there is no tissue grasped between the jaws of the MiSeal Reposable Thermal Ligating Shears as this activity may result in premature degradation of the device.
- Do not touch the device tip while performing the pre-check as this may cause injury.
- Do not touch an electrosurgical (Bovie) electrode to any part of the MiSeal Reposable Thermal Ligating Shears.
- The device is not intended for continuous use. A recommended duty cycle is approximately five (5) to ten (10) seconds on, ten (10) seconds off.
- Only use the MiSeal Reposable Thermal Ligating Shears with the Microline Surgical Universal Power Supply (REF 200-006R). Use of any other power supply may damage the device and could prevent proper function during use.
- Activating the device with excessive force or traction may result in an incomplete seal. If hemostasis is not present, use appropriate techniques to achieve hemostasis.
- Procedures using instruments for sealing and dividing of tissue during surgery should be performed only by persons having adequate training and familiarity with these surgical techniques. Consult the medical literature relative to techniques, complications and hazards prior to performance of any procedure. Surgeons using this device should be familiar with the specific anatomy of the region in which they intend to perform the procedure
- There are no unusual risks associated with the proper disposal of this equipment. Follow any local regulations regarding proper disposal of used disposable components.
- Store in a cool, dry place.

Warnings

- Do not use in the presence of flammable materials (e.g. alcohol, flammable anesthetics).
- Always disconnect the tip and instrument cord from the handpiece before discarding; the UPS and MiSeal Handpiece are reusable.

Contraindications

The MiSeal Reposable Thermal Ligating Shears are not to be used as a fallopian tube sterilization device

Compliance with Standards

When used with the UPS (REF 200-006R), the device complies with IEC60601-1 requirements for type CF applied part and meets electromagnetic compatibility requirements of IEC60601-1-2.

Cleaning - MiSeal Handpiece Only

The tip and instrument cord are to be detached from handpiece and discarded prior to cleaning and sterilization of the handpiece.
1. Prepare an enzymatic solution containing 60 mL of ENZOL® Enzymatic Detergent per 4 L of water at 38° C
2. Remove the luer cap from the flushing port on the shaft.
3. Wipe down the connector receptacle cap with the prepared enzymatic solution, rinse with deionized water and insert into the cable connector receptacle at the bottom of the handpiece.
4. Rinse the device with warm tap water (36° C) for a minimum of one (1) minute.
5. Pre-soak the device in the prepared enzymatic solution for ten (10) minutes.
6. In the prepared enzymatic solution, ensure all moveable assemblies including the triggers and rotator are actuated.
7. Connect a 60 mL luer type syringe filled with the prepared enzymatic solution to the flushing port where the luer cap was removed.
8. Using the syringe, flush the inside of the shaft three (3) times with the enzymatic solution.
9. Remove the syringe and repeat flushing with warm tap water. Flush until clear water exits.
10. Submerge the device under warm water to avoid airborne contaminants. Ensure all moveable assemblies including the triggers and rotator are actuated under water.
11. Make sure that all visible bioburden has been removed.
12. Remove the receptacle cap and rinse the entire device with deionized water for one (1) minute. After the rinse, flush inside of the shaft three (3) times with deionized water for a final rinse.
13. Inspect the device for functionality and package appropriately for sterilization.

Sterilization - MiSeal Handpiece Only:

1. Prior to sterilization, the device must be thoroughly cleaned.
2. Wrap the device.
3. Sterilize the device following the protocol provided by the sterilizer manufacturer.

The following validated steam sterilization cycles are recommended as minimum guidelines:
Gravity Cycle: 4 minutes @ 270°F (132°C) and 20 minutes of drying time
Pre-Vacuum Cycle: 4 minutes @ 270°F (132°C) and 20 minutes of drying time

Return Policy:

Returns must be made within 30 days of shipment and must be in original, unopened packaging. Disposable products must be returned in complete, unopened boxes. Returned product is subject to a 25% restocking fee based on the original purchase price. Prior to returning any device for repair, contact Microline Surgical Customer Service to obtain an RGA. Unauthorized returns will not be accepted. All returns must be shipped freight pre-paid. This device will be returned unrepaired to the sender if the following conditions are not met:
- Proper cleaning and sterilization after last procedure or a declaration of decontamination.
- The device must be assigned an RGA number
- The RGA number must be clearly visible on the outside of the box it is shipped in.

Handpiece validation: The handpiece has been validated for fifty cleaning/sterilization cycles.

Warranty Information for MiSeal Disposable Kit:

All Microline Surgical tips and accessories are unconditionally guaranteed against defects in material and workmanship. Microline Surgical will, at its option and without charge, either repair or replace any tip or accessory which Microline Surgical determines to be defective in material or workmanship when used for its intended surgical purposes.

Warranty Information for MiSeal Handpiece:

Microline Surgical warrants that its devices are free from any defects in both material and workmanship. Microline Surgical shall not be held liable for any incidental or consequential damage of any kind. Reusable handpieces are covered by a one year limited warranty, valid only to the original purchaser of the device. Irrelevant of the nature of the repair, Microline Surgical will return to the customer a "like new" device completely refurbished and upgraded to Microline Surgical factory specifications.
- Gross abuse or neglect of a Microline Surgical device will void this warranty.
- Work performed on a device by anyone other than an authorized service center will void this warranty and will subject the device to a premium repair charge.

Symbol Definition

LATEX Means: Latex Free

EC REP Medical Device Safety Service GmbH
Schiffgraben 41
D-30175 Hannover
Germany

CE 0120

Rx Only

Universal Power Supply Labeling

MICROLINE SURGICAL

ENGLISH

Microline Surgical, Inc.
800 Cummings Center, Suite 166T
800 Cummings Center, Suite 157X
Beverly, MA 01915 U.S.A.
TEL: (978) 922-9810

UPS Universal Power Supply – Model # 200-006R - Instructions For Use
For use only with
Microline Cautery Instruments and Microline PowerPack™ Footswitch
Device Description
The Model # 200-006R Universal Power Supply (UPS) is a non-sterile, reusable, AC powered unit intended to be used only with Microline Cautery Instruments and the PowerPack Footswitch. The UPS is intended to be connected to AC power via a grounded hospital grade power cord and features an on/off switch and green power-on LED indicator. Depending on the device used, up to three operating heat ranges are available from the UPS with corresponding tones indicating the power level of the instruments heating element. A low frequency tone indicates the use of low heat. An interrupted low tone indicates the use of variable heat, and a higher frequency continuous tone indicates the use of high heat levels. If the instrument does not require the use of the PowerPack Footswitch, the UPS will supply power at the variable heat level only, unless a multi-heat range device is used. The UPS may be placed on a flat non-sterile surface adjacent to the sterile field, or may be suspended from a nearby IV pole. If suspended from an IV pole, the UPS may be rotated to face the user.
Intended Use
The UPS is intended for use only with Microline Cautery Instruments and the PowerPack Footswitch for the simultaneous cutting and cauterization of soft tissue during surgery.
1. Connect grounded, Hospital Grade power cord to the UPS AC connector receptacle.
2. Plug the power cord into a grounded Hospital Grade receptacle.
3. Align the key portion of the Microline Cautery Instrument connector with the UPS connector receptacle and insert.
4. If the PowerPack Footswitch is to be used, plug the Footswitch connector into the Footswitch connector receptacle of the UPS.
5. Turn on the UPS.
6. Refer to the appropriate Microline Cautery Instrument and PowerPack Footswitch (if applicable) Instructions For Use for device specific use instructions and pre-check requirements.
7. Model # 200-006R: When the instrument heating element is activated, the UPS emits a tone that will last until the heating element is deactivated. The amount of heat delivered to the instrument heater may be adjusted by pressing the "+" or "-" push pads on the right side of the UPS. The numerical setting is shown on the LED bar graph above the push pads. Increasing the LED's numerical value setting increases the amount of heat delivered to the instrument when using a single-heat range instrument or the variable range when using the optional PowerPack Footswitch accessory or multi-heat range instrument. Generally, lower heat ranges increase the sealing capabilities and increase the time required to divide tissue. Higher heat ranges decrease the time to divide and may decrease seal integrity
8. At the end of the surgical procedure, turn the UPS off and disconnect the Microline Cautery Instrument and if applicable, the PowerPack Footswitch.
Handling, Storage And Cleaning
Do not drop. Store in a cool, dry place. Avoid prolonged exposure to extreme temperatures. Exterior of the UPS may be cleaned using a soft cloth moistened with a solution of water and a mild detergent or disinfectant. Do not immerse the UPS in liquids.
Recommended Environmental Conditions

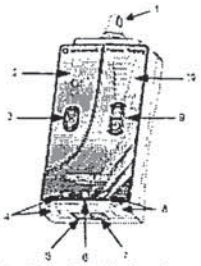
	Transport	Storage	Operating
	-15°C to 50°	-15°C to 50°	-15°C to 50°
	25 to 95	30 to 85	45 to 75
	700hPa to 1060hPa	700hPa to 1060hPa	700hPa to 1060hPa

There are no unusual risks associated with the proper disposal of this equipment. Follow any local regulations regarding proper disposal of used electrical equipment.

Model # 200-006R

Universal Power Supply

1- Hanger
2- Volume LED Indicators
3- Volume Control Buttons
4- Footswitch Connector Receptacle and Indicator
5- AC Connector Receptacle
6- Power On LED Indicator
7- On/Off Switch
8- Cautery Instrument Connector Receptacle and indicator
9- Power Level Control Buttons
10-Power Level LED Indicators



Note: A power cord for North America (U.S. and Canada only) is supplied with the UPS. For other locales, ensure that the appropriate power cord and connector are used, per National Guidelines (i.e. HAR, 250 VAC, 2A, 3 x 0.75 mm2, minimum).
Precautions And Warnings
- When used in the U.S. use only with supplied Hospital Grade power cord connected to Hospital Grade receptacle
- Use only with Microline Cautery Instruments and PowerPack Footswitch. Use of any other instrument may damage the instrument/UPS and could prevent it from functioning properly during use
- Do not drop the UPS
- Do not immerse the UPS in liquids
- Do not sterilize the UPS
- If using multiple Microline Cautery Instruments, do not allow instruments to contact each other. Do not touch electrosurgical (Bovie) electrode to Microline Cautery Instruments.
- Procedures using instruments for cutting/cauterization should be performed only by persons having adequate training and familiarity with these surgical techniques. Consult the medical literature relative to techniques, complications and hazards prior to performance of any procedure. Surgeons using this device should be familiar with the specific anatomy of the region in which they intend to perform the procedure.
- If using the UltraSlim or SC Forceps device, see Instructions For Use for pre-check information.
- There are no user serviceable parts.

Note: The UPS is not intended for continuous use. A typical duty cycle of approximately five (5) seconds on, ten (10) seconds off is recommended. If the UPS is used continuously, or the instrument connector becomes shorted, the output of the UPS may be interrupted. This will be indicated by an absence of audible tone. Attempt to determine the cause of the problem before proceeding. If problem cannot be resolved or power is not restored after several minutes of cool-down, contact Microline Surgical for instructions regarding repair or replacement of the device.
Warning:
Do not use in the presence of flammable materials (e.g. alcohol, flammable anesthetics)
Always disconnect the instrument before discarding; the UPS is reusable.

000076

Electrical Requirements
Input: 100-240 VAC, 50/60 Hz, 100W
Maximum Output: 60W
No Load Voltage: 9V D.C.

Compliance with Standards
The UPS complies with IEC60601-1 (UL 2601-1 and CAN/CSA-C22.2 No. 601.1-M90) requirements for type Class I, Type CF equipment, Type CF applied parts, and meets electromagnetic compatibility requirements of IEC60601-1-2 Avoid use in the proximity of other equipment that may interfere with the proper operation of the UPS.

Limited Warranty
Microline Surgical, Inc. warrants that the UPS will be free from defects in materials and workmanship for a period of one (1) year from shipment invoice provided that the product is used in accordance with applicable instructions. Products found to be defective during this period will be replaced at no charge. Microline makes no other warranties with respect to the product and expressly disclaims all other warranties expressed or implied, as to merchantability, fitness for any particular purpose or any other matter In no event shall Microline Surgical, Inc. be liable for consequential damages.

Symbol Definition


Means: Does not Contain Latex

Means: Footswitch Connector

Means: Off (Power disconnected from the main.


Means. Temperature

Means Relative Humidity.

Means: Instrument Connector.


Means: On (Power connected to the mains)

Means. Atmospheric Pressure.

Means. Type CF applied Part

EC REP **Medical Device Safety Service GmbH**
Schiffgraben 41
D-30175 Hannover
Germany

CE 0120

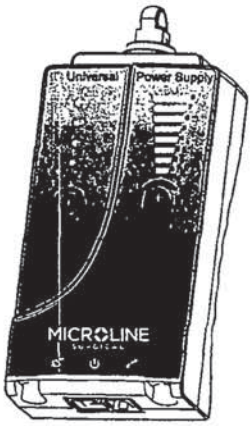
Rx Only

IFU0035 Rev D

000077

Universal Power Supply

REF 200-006R SN



Rx Only

See Instructions For Use. Do Not Drop.
Siehe Gebrauchsanweisung. Nicht fallen lassen.
Consulte las instrucciones de uso. No deje caer este dispositivo.
Consulter le mode d'emploi. Ne pas laisser tomber.
Vedere le istruzioni per l'uso. Non lasciare cadere.
Zie gebruiksaanwijzing. Niet laten vallen.
Consulte as instruções de utilização. Não deixe cair.
Kullanım Yönergeleri'ne bakın. Yere Düşürmeyin.

MICROLINE SURGICAL

Microline Surgical, Inc.
800 Cummings Center, Suite 16GT
800 Cummings Center, Suite 157X
Beverly, MA 01915 U.S.A.

	Transport	Storage
	-15°C to 50°C	15°C to 30°C
	25 to 95	30 to 85
	700hPa to 1060hPa	700hPa to 1060hPa

EC REP Medical Device Safety Service GmbH
Schiffgraben 41
D-30175 Hannover
Germany

CE 0120

LBL0109 Rev E

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14

Sterilization and Shelf Life

14. Sterilization and Shelf Life

Sterilization:

1. The MiSeal Thermal Ligating Shears Kit has been validated to a SAL of $1x10^{-6}$ using gamma radiation, to a minimum dose of 25 kGy and a maximum dose of 40 kGy.
2. The Gamma sterilization process has been validated to the following standards:
   - Clause 9, *Method VDmax – Substantiation of 25 kGy or 15 kGy as the sterilization dose in ISO 11137-2:2006*

Packaging and Shelf Life:

1. The packaging materials for the MiSeal Thermal Ligating Shears Kit 5mm curved jaw and disposable cable (sterile disposables) are:
   - Sterile Barrier: Tyvek (b)(4) Mylar (b)(4) pouch with 15°chevron 5 5/8" wide, 19" long
   - Packing Insert, MiSeal Disposable Tip Kit, 20 point chipboard
   - Product Box, (b)(4) clay coated solid bleached sulphate chipboard 3.5" x1.5" x 14"

2. Shelf Life aging parameters were determined using the Arrhenius equation defined in ASTM F1980 Standard Guide for Accelerated Aging for Sterile Medical Devices. Samples were representative of the final configuration including sterilization. The following tests were conducted:

(b)(4)

- Visual Inspection for packaging, curved jaw and cable
- Electrical compliance tested, cable, pin to pin resistance values and continuity
- Mechanical pull testing performed on the assembled 5mm jaw and cable
- Electrical performance testing of the assembly for tip electrical performance
- Bench testing of the system was performed for 100 simulated use activations.

Conclusion:

(b)(4)

3. Ship testing was performed to validate the ability of the package systems to protect the MiSeal Reposable Handle and the MiSeal Disposable Tip Kit from hazards typically associated with the shipping and distribution environment. Testing was performed to ASTM D4169-01 Standard Practice for Performance Testing of Shipping Containers and Systems using distribution Cycle 13.

Samples Prepared Prior to Testing

In addition to the packaging described above for the MiSeal Thermal Ligating Shears Kit, 5 product boxes were placed in a regular slotted container (b)(4) that constitutes the shipping container.

The MiSeal handpiece assembly was also tested and each unit was placed in a Roll end Tuck Top container with an (b)(4) pad.

Test Procedure:

(b)(4)

Results

(b)(4)

Vehicle Stacking Test

(b)(4)

Loose Load Vibration Test

(b)(4)

Results

(b)(4)

Vehicle Vibration Test

(b)(4)

Results

(b)(4)

Concentrated Impact Test

(b)(4)

Final Manual Handling Test

(b)(4)

Gross Leak Test (Bubble)

(b)(4)

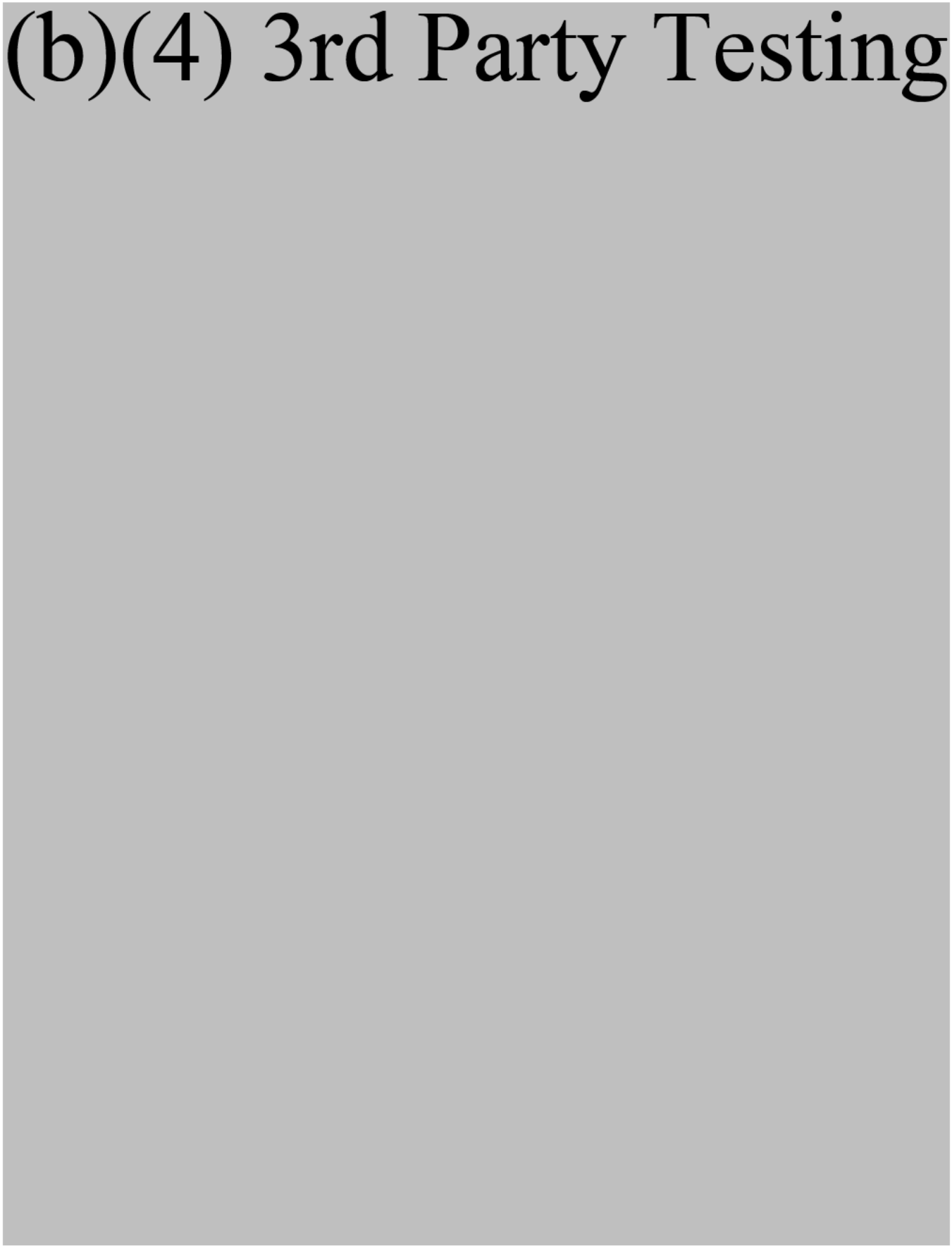
Results

(b)(4)

Seal Strength Test (Peal)

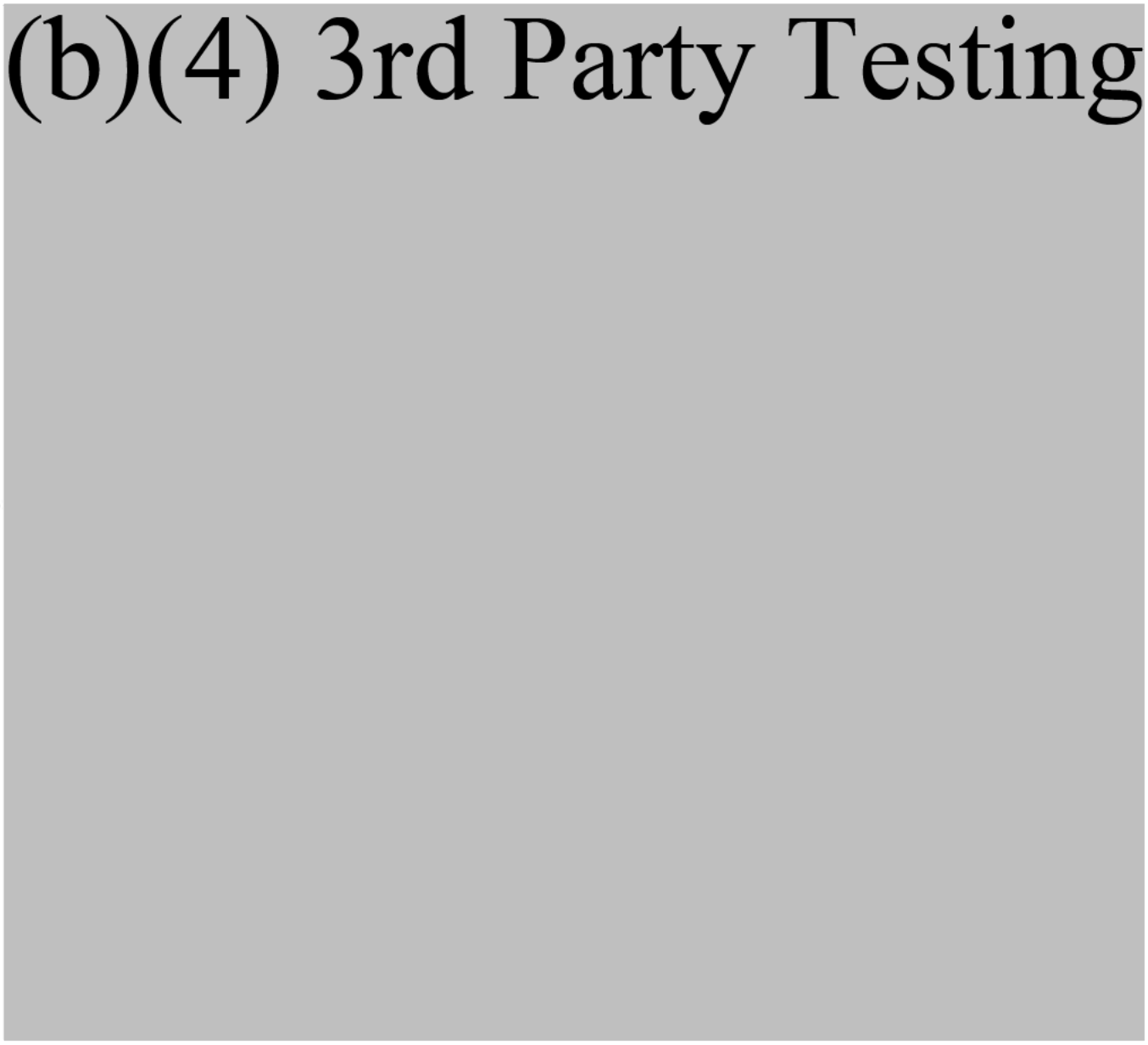
(b)(4)

(b)(4) 3rd Party Testing



(b)(4) 3rd Party Testing

Sterilization Validation of the MiSeal Reposable (reusable) Handpiece



(b)(4) 3rd Party Testing

(b)(4) 3rd Party Testing

Cleaning Validation Protocol and Report: HYDRA Handle Assembly

(b)(4) Validation or Verification Testing

(b)(4) Validation or Verification Testing

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Appendix 4 – Device History Record
(84 pages)

(b)(4)Engineering Drawing

(b)(4)Engineering Drawing

(b)(4)Engineering Drawing

(b)(4)Engineering Drawing

Line Item #	Part #	Description	Qty
1	ASM0184	Assy, Switching Module	1
2	IFU0039	IFU, Hydra	1
3	LBL0120	Label, Packaging, Handle, Hyrda	1
4	MAT0132	Flux, Inorganic Acid, Water Soluble	AR
5	MAT0175	NiTi, Rectangular	.91"
6	MAT0176	Heatshrink Tubing, MT-3000 3/16	1 x 0.74" 1 x 13.00"
7	MAT0183	PTFE Heat Shrink, 2 to 1, 5 Gauge, Lightweight Wall	0.42"
8	MAT0184	Solder, Lead-Free, 95 Sn/5 Sb	AR
9	MAT0185	Silicone Fluid	AR
10	PRT0956	Receptacle, 3 Conductor, 18AWG	1
11	PRT0961	Handle, Hydra, Left	1
12	PRT0962	Handle, Hydra, Right	1
13	PRT0963	Contact, Inner Rotator, Hydra	1
14	PRT0965	Finger Button, Hydra	1
15	PRT0966	Contact, Outer Rotator, Hydra	1
16	PRT0975	PEEK Overmolded Wire, 20 AWG	0.09 (6.30")
17	PRT0982	Tube, Outer, 35C, Hydra	1
18	PRT0984	Rotator, 5-Flute, Hydra	1
19	PRT0985	Rod, Guide, 35C, Hydra	1
20	PRT0988	Trigger, Thumb, Hydra	1
21	PRT0991	Cap, Bellows, Finger Button	1
22	PRT0992	Cap, Bellows, Interlock	1
23	PRT1001	Switch, Rocker	1
24	PRT1006	Plunger, Spring, Round-Nose, .125 Dia	2
25	PRT1017	Pin, Pivot, Hydra	1
26	PRT1020	Guide, Plunger, Rocker, Left	1
27	PRT1021	Guide, Plunger, Rocker, Right	1
28	PRT1022	Screw, Plastite, Torx, Pan Head, SS, 2-28 x .250	MW 3/16/10 5 3
29	PRT1023	Screw, Plastite, Torx, Pan Head, SS, 2-28 x .375	2
30	PRT1024	Screw, Plastite, Torx, Pan Head, SS, 2-28 x .500	MW 3/16/10 2 1
31	PRT1026	Screw, Plastite, Torx, Pan Head, SS, 4-20 x .500	2
32	PRT1027	Cap, Luer Lock, 2-Piece, Hydra	1
33	PRT1028	Tether, Luer Cap	1
34	PRT1029	Plug, Receptacle, Molded	1
35	PRT1039	O-Ring, Guide Rod, Hydra	1
36	PRT1040	Support Ring	2
37	PRT1041	Insert, Foam, Packaging, Hydra	1
38	PRT1042	Pad, Cover, Hydra	1
39	PRT1043	Box, Handle, Hydra	1
40	PRT1044	Clip, Retention, Outer Tube, Hydra	1
41	PRT1046	Set Screw, Socket, Cup Point, SS, 6-32 x .125	1
42	PRT1057	Proximal Insulator	1
43	MPI0096	MPI, Hydra Reposable Handpiece Assy	Doc
44	TRV0099	Traveler, Hydra Reposable Handpiece Assy	Doc
45	N/A	Screw, Plastite, Torx, Pan Head, SS, 4-20x.500	2
46	N/A	Screw, Plastite, Torx, Pan Head, SS, 2-28x.750	1

MW 3/6/10

(b)(4) Manufacturing Process Instructions

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Line Item #	Part #	Description	Qty
1	MAT0005-03	Solder, Activated Rosin Core, 3.3% Flux, 63-37 Tin-Lead	AR
2	MAT0177	Wire, 20 AWG, Teflon Jacket, Light Blue	2.45"
3	MAT0179	Loctite HVAC Blue Pipe Joint Compound	AR
4	MAT0180	Wire, 20 AWG, Teflon Jacket, Red	1.85"
5	MAT0184	Solder, Lead-Free, 95 Sn/5 Sb	AR
6	MAT0186	Wire, 24 AWG, Teflon Jacket, White	0.58"
7	MAT0187	Loctite 222 Threadlocker	AR
8	PRT0960	Switch, High Amperage	1
9	PRT0964	Spring, Plunger, Finger Button	1
10	PRT0969	Plunger, Finger Button	1
11	PRT0970	Bellows, Finger Button	1
12	PRT0971	Bellows, Interlock	1
13	PRT0974	Overmold Plug, Threaded	1
14	PRT0976	Housing, Switching Module	1
15	PRT0977	Lid, Switching Module	1
16	PRT0978	Seal, Switching Module	1
17	PRT0979	Screw, Phillips, Flat Head, SS, 2-56 x .250	7
18	PRT0990	Switch, Low Current	2
19	PRT0993	Plunger, Interlock, Floating	1
20	PRT0994	Plunger, Interlock, Main	1
21	PRT1004	Ring, Retaining, E-Style, .1406	1
22	PRT1007	Spring, Plunger, Interlock, Floating	1
23	PRT1008	Spring, Plunger, Interlock, Main	1
24	PRT1009	Spring, Garter, Canted	1
25	PRT1010	Plug, Switch Mount, Low Current	1
26	PRT1011	Switch Mount, Low Current	1
27	PRT1012	Set Screw, Socket, Dog Point, SS, 2-56 x .125	1
28	PRT1013	Screw, Phillips, Pan Head, SS, 2-56 x .313	2
29	PRT1014	Screw, Cap, Socket Head, SS, 2-56 x .313	2
30	PRT1016	Pin, Plunger, Finger Button	1
31	PRT1019	O-Ring, Switching Module Housing	1
32	PRT1030	Eyelet, .059 OD x .045 ID x .062	8
33	PRT1038	Resistor, Wirewound, 3.3k, 1/4W	1
34	MPI0100	MPI, Switching Module Assy	Doc
35	TRV0104	Traveler, Switching Module Assy	Doc

(b)(4)Manufacturing Process Instruction

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Line Item #	Part #	Description	Qty
1	ASM0184	Assy, Switching Module	1
2	IFU0039	IFU, Hydra	1
3	LBL0120	Label, Packaging, Handle, Hyrda	1
4	MAT0132	Flux, Inorganic Acid, Water Soluble	AR
5	MAT0175	NiTi, Rectangular	.91"
6	MAT0176	Heatshrink Tubing, MT-3000 3/16	1 x 0.74" 1 x 13.00"
7	MAT0183	PTFE Heat Shrink, 2 to 1, 5 Gauge, Lightweight Wall	0.42"
8	MAT0184	Solder, Lead-Free, 95 Sn/5 Sb	AR
9	MAT0185	Silicone Fluid	AR
10	PRT0956	Receptacle, 3 Conductor, 18AWG	1
11	PRT0961	Handle, Hydra, Left	1
12	PRT0962	Handle, Hydra, Right	1
13	PRT0963	Contact, Inner Rotator, Hydra	1
14	PRT0965	Finger Button, Hydra	1
15	PRT0966	Contact, Outer Rotator, Hydra	1
16	PRT0975	PEEK Overmolded Wire, 20 AWG	0.09 (6.30")
17	PRT0982	Tube, Outer, 35C, Hydra	1
18	PRT0984	Rotator, 5-Flute, Hydra	1
19	PRT0985	Rod, Guide, 35C, Hydra	1
20	PRT0988	Trigger, Thumb, Hydra	1
21	PRT0991	Cap, Bellows, Finger Button	1
22	PRT0992	Cap, Bellows, Interlock	1
23	PRT1001	Switch, Rocker	1
24	PRT1006	Plunger, Spring, Round-Nose, .125 Dia	2
25	PRT1017	Pin, Pivot, Hydra	1
26	PRT1020	Guide, Plunger, Rocker, Left	1
27	PRT1021	Guide, Plunger, Rocker, Right	1
28	PRT1022	Screw, Plastite, Torx, Pan Head, SS, 2-28 x .250	NW 3/6/10 5 3
29	PRT1023	Screw, Plastite, Torx, Pan Head, SS, 2-28 x .375	2
30	PRT1024	Screw, Plastite, Torx, Pan Head, SS, 2-28 x .500	NW 3/6/10 2 1
31	PRT1026	Screw, Plastite, Torx, Pan Head, SS, 4-20 x .500	2
32	PRT1027	Cap, Luer Lock, 2-Piece, Hydra	1
33	PRT1028	Tether, Luer Cap	1
34	PRT1029	Plug, Receptacle, Molded	1
35	PRT1039	O-Ring, Guide Rod, Hydra	1
36	PRT1040	Support Ring	2
37	PRT1041	Insert, Foam, Packaging, Hydra	1
38	PRT1042	Pad, Cover, Hydra	1
39	PRT1043	Box, Handle, Hydra	1
40	PRT1044	Clip, Retention, Outer Tube, Hydra	1
41	PRT1046	Set Screw, Socket, Cup Point, SS, 6-32 x .125	1
42	PRT1057	Proximal Insulator	1
43	MPI0096	MPI, Hydra Reposable Handpiece Assy	Doc
44	TRV0099	Traveler, Hydra Reposable Handpiece Assy	Doc
45	N/A	Screw, Plastite, Torx, Pan Head, SS, 4-20x.500	2
46	N/A	Screw, Plastite, Torx, Pan Head, SS, 2-28x.750	1

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Line Item #	Part #	Description	Qty
1	MAT0005-03	Solder, Activated Rosin Core, 3.3% Flux, 63-37 Tin-Lead	AR
2	MAT0177	Wire, 20 AWG, Teflon Jacket, Light Blue	2.45"
3	MAT0179	Loctite HVAC Blue Pipe Joint Compound	AR
4	MAT0180	Wire, 20 AWG, Teflon Jacket, Red	1.85"
5	MAT0184	Solder, Lead-Free, 95 Sn/5 Sb	AR
6	MAT0186	Wire, 24 AWG, Teflon Jacket, White	0.58"
7	MAT0187	Loctite 222 Threadlocker	AR
8	PRT0960	Switch, High Amperage	1
9	PRT0964	Spring, Plunger, Finger Button	1
10	PRT0969	Plunger, Finger Button	1
11	PRT0970	Bellows, Finger Button	1
12	PRT0971	Bellows, Interlock	1
13	PRT0974	Overmold Plug, Threaded	1
14	PRT0976	Housing, Switching Module	1
15	PRT0977	Lid, Switching Module	1
16	PRT0978	Seal, Switching Module	1
17	PRT0979	Screw, Phillips, Flat Head, SS, 2-56 x .250	7
18	PRT0990	Switch, Low Current	2
19	PRT0993	Plunger, Interlock, Floating	1
20	PRT0994	Plunger, Interlock, Main	1
21	PRT1004	Ring, Retaining, E-Style, .1406	1
22	PRT1007	Spring, Plunger, Interlock, Floating	1
23	PRT1008	Spring, Plunger, Interlock, Main	1
24	PRT1009	Spring, Garter, Canted	1
25	PRT1010	Plug, Switch Mount, Low Current	1
26	PRT1011	Switch Mount, Low Current	1
27	PRT1012	Set Screw, Socket, Dog Point, SS, 2-56 x .125	1
28	PRT1013	Screw, Phillips, Pan Head, SS, 2-56 x .313	2
29	PRT1014	Screw, Cap, Socket Head, SS, 2-56 x .313	2
30	PRT1016	Pin, Plunger, Finger Button	1
31	PRT1019	O-Ring, Switching Module Housing	1
32	PRT1030	Eyelet, .059 OD x .045 ID x .062	8
33	PRT1038	Resistor, Wirewound, 3.3k, 1/4W	1
34	MPI0100	MPI, Switching Module Assy	Doc
35	TRV0104	Traveler, Switching Module Assy	Doc

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APPENDIX 4 – Device History Record
(79 pages)

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Line Item #	Part #	Description	Qty
1	ASM0184	Assy, Switching Module	1
2	IFU0039	IFU, Hydra	1
3	LBL0120	Label, Packaging, Handle, Hyrda	1
4	MAT0132	Flux, Inorganic Acid, Water Soluble	AR
5	MAT0175	NiTi, Rectangular	.91"
6	MAT0176	Heatshrink Tubing, MT-3000 3/16	1 x 0.74" 1 x 13.00"
7	MAT0183	PTFE Heat Shrink, 2 to 1, 5 Gauge, Lightweight Wall	0.42"
8	MAT0184	Solder, Lead-Free, 95 Sn/5 Sb	AR
9	MAT0185	Silicone Fluid	AR
10	PRT0956	Receptacle, 3 Conductor, 18AWG	1
11	PRT0961	Handle, Hydra, Left	1
12	PRT0962	Handle, Hydra, Right	1
13	PRT0963	Contact, Inner Rotator, Hydra	1
14	PRT0965	Finger Button, Hydra	1
15	PRT0966	Contact, Outer Rotator, Hydra	1
16	PRT0975	PEEK Overmolded Wire, 20 AWG	0.09 (6.30")
17	PRT0982	Tube, Outer, 35C, Hydra	1
18	PRT0984	Rotator, 5-Flute, Hydra	1
19	PRT0985	Rod, Guide, 35C, Hydra	1
20	PRT0988	Trigger, Thumb, Hydra	1
21	PRT0991	Cap, Bellows, Finger Button	1
22	PRT0992	Cap, Bellows, Interlock	1
23	PRT1001	Switch, Rocker	1
24	PRT1006	Plunger, Spring, Round-Nose, .125 Dia	2
25	PRT1017	Pin, Pivot, Hydra	1
26	PRT1020	Guide, Plunger, Rocker, Left	1
27	PRT1021	Guide, Plunger, Rocker, Right	1
28	PRT1022	Screw, Plastite, Torx, Pan Head, SS, 2-28 x .250	MW 3/6/10 ~~5~~ 3
29	PRT1023	Screw, Plastite, Torx, Pan Head, SS, 2-28 x .375	2
30	PRT1024	Screw, Plastite, Torx, Pan Head, SS, 2-28 x .500	MW 7/8/10 ~~2~~ 1
31	PRT1026	Screw, Plastite, Torx, Pan Head, SS, 4-20 x .500	2
32	PRT1027	Cap, Luer Lock, 2-Piece, Hydra	1
33	PRT1028	Tether, Luer Cap	1
34	PRT1029	Plug, Receptacle, Molded	1
35	PRT1039	O-Ring, Guide Rod, Hydra	1
36	PRT1040	Support Ring	2
37	PRT1041	Insert, Foam, Packaging, Hydra	1
38	PRT1042	Pad, Cover, Hydra	1
39	PRT1043	Box, Handle, Hydra	1
40	PRT1044	Clip, Retention, Outer Tube, Hydra	1
41	PRT1046	Set Screw, Socket, Cup Point, SS, 6-32 x .125	1
42	PRT1057	Proximal Insulator	1
43	MPI0096	MPI, Hydra Reposable Handpiece Assy	Doc
44	TRV0099	Traveler, Hydra Reposable Handpiece Assy	Doc
45	N/A	Screw, Plastite, Torx, Pan Head, SS, 4-20x.500	2
46	N/A	Screw, Plastite, Torx, Pan Head, SS, 2-28x.750	1

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Line Item #	Part #	Description	Qty
1	MAT0005-03	Solder, Activated Rosin Core, 3.3% Flux, 63-37 Tin-Lead	AR
2	MAT0177	Wire, 20 AWG, Teflon Jacket, Light Blue	2.45"
3	MAT0179	Loctite HVAC Blue Pipe Joint Compound	AR
4	MAT0180	Wire, 20 AWG, Teflon Jacket, Red	1.85"
5	MAT0184	Solder, Lead-Free, 95 Sn/5 Sb	AR
6	MAT0186	Wire, 24 AWG, Teflon Jacket, White	0.58"
7	MAT0187	Loctite 222 Threadlocker	AR
8	PRT0960	Switch, High Amperage	1
9	PRT0964	Spring, Plunger, Finger Button	1
10	PRT0969	Plunger, Finger Button	1
11	PRT0970	Bellows, Finger Button	1
12	PRT0971	Bellows, Interlock	1
13	PRT0974	Overmold Plug, Threaded	1
14	PRT0976	Housing, Switching Module	1
15	PRT0977	Lid, Switching Module	1
16	PRT0978	Seal, Switching Module	1
17	PRT0979	Screw, Phillips, Flat Head, SS, 2-56 x .250	7
18	PRT0990	Switch, Low Current	2
19	PRT0993	Plunger, Interlock, Floating	1
20	PRT0994	Plunger, Interlock, Main	1
21	PRT1004	Ring, Retaining, E-Style, .1406	1
22	PRT1007	Spring, Plunger, Interlock, Floating	1
23	PRT1008	Spring, Plunger, Interlock, Main	1
24	PRT1009	Spring, Garter, Canted	1
25	PRT1010	Plug, Switch Mount, Low Current	1
26	PRT1011	Switch Mount, Low Current	1
27	PRT1012	Set Screw, Socket, Dog Point, SS, 2-56 x .125	1
28	PRT1013	Screw, Phillips, Pan Head, SS, 2-56 x .313	2
29	PRT1014	Screw, Cap, Socket Head, SS, 2-56 x .313	2
30	PRT1016	Pin, Plunger, Finger Button	1
31	PRT1019	O-Ring, Switching Module Housing	1
32	PRT1030	Eyelet, .059 OD x .045 ID x .062	8
33	PRT1038	Resistor, Wirewound, 3.3k, 1/4W	1
34	MPI0100	MPI, Switching Module Assy	Doc
35	TRV0104	Traveler, Switching Module Assy	Doc

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Starion Instruments
Bill of Materials
ECO# XXXX

ASM0180:
Assy, Hydra 35cm Reposable Handpiece

BOM0125
Rev. 1

Line Item #	Part #	Description	Qty
1	ASM0184	Assy, Switching Module	1
2	IFU0039	IFU, Hydra	1
3	LBL0120	Label, Packaging, Handle, Hyrda	1
4	MAT0132	Flux, Inorganic Acid, Water Soluble	AR
5	MAT0175	NiTi, Rectangular	.91"
6	MAT0176	Heatshrink Tubing, MT-3000 3/16	1 x 0.74" 1 x 13.00"
7	MAT0183	PTFE Heat Shrink, 2 to 1, 5 Gauge, Lightweight Wall	0.42"
8	MAT0184	Solder, Lead-Free, 95 Sn/5 Sb	AR
9	MAT0185	Silicone Fluid	AR
10	PRT0956	Receptacle, 3 Conductor, 18AWG	1
11	PRT0961	Handle, Hydra, Left	1
12	PRT0962	Handle, Hydra, Right	1
13	PRT0963	Contact, Inner Rotator, Hydra	1
14	PRT0965	Finger Button, Hydra	1
15	PRT0966	Contact, Outer Rotator, Hydra	1
16	PRT0975	PEEK Overmolded Wire, 20 AWG	0.09 (6.30")
17	PRT0982	Tube, Outer, 35C, Hydra	1
18	PRT0984	Rotator, 5-Flute, Hydra	1
19	PRT0985	Rod, Guide, 35C, Hydra	1
20	PRT0988	Trigger, Thumb, Hydra	1
21	PRT0991	Cap, Bellows, Finger Button	1
22	PRT0992	Cap, Bellows, Interlock	1
23	PRT1001	Switch, Rocker	1
24	PRT1006	Plunger, Spring, Round-Nose, .125 Dia	2
25	PRT1017	Pin, Pivot, Hydra	1
26	PRT1020	Guide, Plunger, Rocker, Left	1
27	PRT1021	Guide, Plunger, Rocker, Right	1
28	PRT1022	Screw, Plastite, Torx, Pan Head, SS, 2-28 x .250	NW 3/6/10 ~~5~~ 3
29	PRT1023	Screw, Plastite, Torx, Pan Head, SS, 2-28 x .375	2
30	PRT1024	Screw, Plastite, Torx, Pan Head, SS, 2-28 x .500	NW 3/6/10 ~~2~~ 1
31	PRT1026	Screw, Plastite, Torx, Pan Head, SS, 4-20 x .500	2
32	PRT1027	Cap, Luer Lock, 2-Piece, Hydra	1
33	PRT1028	Tether, Luer Cap	1
34	PRT1029	Plug, Receptacle, Molded	1
35	PRT1039	O-Ring, Guide Rod, Hydra	1
36	PRT1040	Support Ring	2
37	PRT1041	Insert, Foam, Packaging, Hydra	1
38	PRT1042	Pad, Cover, Hydra	1
39	PRT1043	Box, Handle, Hydra	1
40	PRT1044	Clip, Retention, Outer Tube, Hydra	1
41	PRT1046	Set Screw, Socket, Cup Point, SS, 6-32 x .125	1
42	PRT1057	Proximal Insulator	1
43	MPI0096	MPI, Hydra Reposable Handpiece Assy	Doc
44	TRV0099	Traveler, Hydra Reposable Handpiece Assy	Doc
45	N/A	Screw, Plastite, Torx, Pan Head, SS, 4-20x.500	2
46	N/A	Screw, Plastite, Torx, Pan Head, SS, 2-28x.750	1

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Line Item #	Part #	Description	Qty
1	MAT0005-03	Solder, Activated Rosin Core, 3.3% Flux, 63-37 Tin-Lead	AR
2	MAT0177	Wire, 20 AWG, Teflon Jacket, Light Blue	2.45"
3	MAT0179	Loctite HVAC Blue Pipe Joint Compound	AR
4	MAT0180	Wire, 20 AWG, Teflon Jacket, Red	1.85"
5	MAT0184	Solder, Lead-Free, 95 Sn/5 Sb	AR
6	MAT0186	Wire, 24 AWG, Teflon Jacket, White	0.58"
7	MAT0187	Loctite 222 Threadlocker	AR
8	PRT0960	Switch, High Amperage	1
9	PRT0964	Spring, Plunger, Finger Button	1
10	PRT0969	Plunger, Finger Button	1
11	PRT0970	Bellows, Finger Button	1
12	PRT0971	Bellows, Interlock	1
13	PRT0974	Overmold Plug, Threaded	1
14	PRT0976	Housing, Switching Module	1
15	PRT0977	Lid, Switching Module	1
16	PRT0978	Seal, Switching Module	1
17	PRT0979	Screw, Phillips, Flat Head, SS, 2-56 x .250	7
18	PRT0990	Switch, Low Current	2
19	PRT0993	Plunger, Interlock, Floating	1
20	PRT0994	Plunger, Interlock, Main	1
21	PRT1004	Ring, Retaining, E-Style, .1406	1
22	PRT1007	Spring, Plunger, Interlock, Floating	1
23	PRT1008	Spring, Plunger, Interlock, Main	1
24	PRT1009	Spring, Garter, Canted	1
25	PRT1010	Plug, Switch Mount, Low Current	1
26	PRT1011	Switch Mount, Low Current	1
27	PRT1012	Set Screw, Socket, Dog Point, SS, 2-56 x .125	1
28	PRT1013	Screw, Phillips, Pan Head, SS, 2-56 x .313	2
29	PRT1014	Screw, Cap, Socket Head, SS, 2-56 x .313	2
30	PRT1016	Pin, Plunger, Finger Button	1
31	PRT1019	O-Ring, Switching Module Housing	1
32	PRT1030	Eyelet, .059 OD x .045 ID x .062	8
33	PRT1038	Resistor, Wirewound, 3.3k, 1/4W	1
34	MPI0100	MPI, Switching Module Assy	Doc
35	TRV0104	Traveler, Switching Module Assy	Doc

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Biocompatibility Testing

15. Biocompatibility Testing

Biocompatibility was conducted in accordance with ANSI/AAMI/ISO 10993-1. The MiSeal Reposable Thermal Ligating Shear falls into the category of external communicating device, Tissue/bone/dentin, limited contact duration (less than 24 hours) as described by Table A.1 in Annex A of ANSI/AAMI/ISO 10993-1.

The testing required by the table consists of Cytotoxicity, Sensitization and Irritation or Intracutaneous reactivity. Testing performed on the TLS2 Starion Instruments 510(k) K002547 contained exactly the same patient contacting materials as those used in the design and manufacture of the MiSeal Reposable Thermal Ligating Shears. Additionally, exactly the same materials were used in the manufacture of the Thermal Ligating Shears (TLS3) K062257 which is the predicate device in this submission. Microline acquired Starion Instruments. This is how it is known that the materials are identical.

Testing performed consisted of the following:

- Cytotoxicity Study Using the ISO Elution Method
- *In Vitro* Hemolysis Study
- ISO Intracutaneous Study
- USP and ISO Systemic Toxicity Study
- ISO Maximization Study

The requirements of ANSI/AAMI/ISO 10993-1 were fulfilled.

See the attached test results.

(b)(4) 3rd Party Testing

(b)(4) 3rd Party Testing

(b)(4) 3rd Party Testing

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(b)(4) 3rd Party Testing

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Software

16. Software

This section is not applicable because there is no software in the MiSeal Reposable Thermal Ligating Shears, nor in any of the accessories used with the MiSeal Reposable Thermal Ligating Shears.

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Electromagnetic Compatibility and Electrical Safety

Summary Report

EN 60601-1-2:2007

Scope: Describe extent of conformance of the device to this standard.

Item	Result
Adaptations used to adapt to the device under review (for example, alternative test methods)	No adaptations were used to adapt the device under review.
Choices made when options or a selection of methods are described	No choices were made due to options or selection of methods.
Deviations from the standard	No deviations were made from the requirements in EN60601-1-2:2007 or IEC 60601-1-2:2007.
Requirements not applicable to the device	The tested sample complied with the emission and susceptibility requirements of EN60601-1-2:2007 and IEC 60601-1-2:2007.
Name and Address of the test laboratory or certification body involved in conformance assessment to this standard.	(b)(4) 3rd Party Testing

Conclusion
The tested sample conformed to the standard.

17. EMC and Electrical Testing

TABLE OF CONTENTS

Summary Report

IEC 60601-1:1988 + A1:1991 + A2:1995

Scope: Describe extent of conformance of the device to this standard.

Item	Result
Adaptations used to adapt to the device under review (for example, alternative test methods)	No adaptations were used to adapt the device under review to comply with the standard.
Choices made when options or a selection of methods are described	No choices were made due to options or selection of methods for the general requirements for safety and essential performance.
Deviations from the standard	No deviations were made from the requirements in IEC 60601-1:1988 + A1:1991 + A2:1995.
Requirements not applicable to the device	The tested sample complied with the general requirements for safety and essential performance of IEC 60601-1:1988 + A1:1991 + A2:1995. All applicable requirements were addressed. Requirements that were not applicable (such as no moving parts, no suspended masses, no X-Radiation, no pressure vessels, no batteries, no auxiliary mains sockets, no appliance inlet, no oil containers, etc) were identified in the test report as 'N/A'
Name and Address of the test laboratory or certification body involved in conformance assessment to this standard.	(b)(4) 3rd Party Testing

Conclusion
The tested sample conformed to the standard.

17. Electromagnetic Compatibility and Electrical Safety

TEST REPORT

EN 60601-1-2:2007

(b)(4) 3rd Party Testing

(b)(4) 3rd Party Testing

REFERENCE 2

Using IEC 60601-1-2 for Testing Medical Devices

By Gary Fenical

Instrument Specialties Company, Inc. (Delaware Water Gap, PA)

As the electromagnetic spectrum becomes increasingly congested and electronic devices proliferate, ensuring electromagnetic compatibility (EMC) in electrical and electronic equipment becomes a critical issue.

Ensuring EMC is a vital issue for companies producing electrical and electronic medical devices. These types of devices must perform as intended and not interfere with other equipment, or the results could be catastrophic. For medical manufacturers, making sure that devices meet EMC standards is not only a marketing necessity, but also a societal concern.

There are several EMC specifications, but none of them alone will provide appropriate testing guidelines for specialized medical devices. To reduce confusion and ensure that devices will be properly tested, medical manufacturers should use an existing standard as a guide for developing a customized testing plan.

IEC 60601-1-2

The International Electrotechnical Commission (IEC) is a worldwide body that promotes international standardization in electronics. In 1993 it released the 60601-1-2 standard, "Medical Electrical Equipment—Part 1: General Requirements for Safety, Amendment No. 2. Collateral Standard: Electromagnetic Compatibility Requirements and Tests."1

The IEC 60601 standard offers a solid basis for medical device testing. Although they are relatively new, the IEC 60601-1-2 requirements have quickly become recognized throughout the world and are instrumental in testing to the European Medical Devices Directive. Organizations such as the American National Standards Institute (ANSI) use the IEC 60601 standard as a basis for their own requirements.

This document specifies acceptable levels for immunity and refers to other documents to specify emission levels. However, these levels may not be strict enough to ensure that equipment will operate as intended. Manufacturers should use the IEC specifications as a guide but tailor them to produce product-specific limits.

Test Specifications and Limits

The IEC 60601-1-2 standard specifies test limits for emissions, immunity, electrostatic discharge (ESD), radiated RF electromagnetic fields, bursts, and surges.

Emissions. Equipment should comply with the conducted and radiated emissions requirements of the International Special Committee on Radio Interference (CISPR). Classification of equipment for this purpose is based on intended use and determined by the manufacturer.

Equipment may be tested for emissions at a standard test site, which would include a turntable and ground plane, and have known attenuation curves. Equipment may also be tested after it has been installed on the users' premises. It is recognized that medical equipment may have unique installation considerations and that type-testing of the installation is the only practical solution to demonstrate compliance to the requirements.

Manufacturers should refer to CISPR 11 for the appropriate requirements and amplitude levels once the class of equipment and test location have been determined.2

Currently, there are no requirements for low-frequency emissions, harmonic distortion, and voltage fluctuations, but some equipment that operate in an intermittent mode will have to meet specific variations of the CISPR 14 Click requirements.3

CISPR 11 covers a frequency range from 150 kHz to 18 GHz. Conducted emissions for low- and medium-voltage power mains (100–415 V) are performed from 150 kHz to 30 MHz. The frequency range for radiated emissions is from 150 kHz to 18 GHz. Depending on the class and use of the equipment, various frequency ranges may be defined. Only the magnetic component of the radiated field is measured from 150 kHz to 30 MHz. Above 30 MHz, both the vertical and horizontal components of the field must be measured.

Amplitude limits in general are established to protect the public broadcast services, not for equipment that may have to operate in close proximity to sensitive medical equipment.

The specification also refers to frequencies designated by the International Telecommunication Union: 2450 MHz for industrial, 5800 MHz for scientific, and 24,125 MHz for medical equipment.

Immunity. General immunity requirements are specified in IEC 60601-1-2. Test levels are given and test methods are based on the IEC 801 series of immunity requirements. If lower limits are justified, accompanying documents should explain this and describe any action that will, as a consequence, be taken by the installer or user.

Accompanying documents should include guidelines for avoiding or identifying and resolving adverse electromagnetic effects. If the use of the equipment is restricted because of its electromagnetic characteristics, relevant restrictions should be described in the accompanying documents.

Compliance with the requirements should be checked by verifying that the equipment continues to perform its intended functions as specified by the manufacturer or fails without creating a safety hazard.

ESD. Equipment should comply with the current edition of IEC 801-2.4 A limit of 3 kV applies for direct contact discharge to all conductive accessible parts and coupling planes. A limit of
8 kV applies for air discharge to nonconductive accessible parts.

Radiated Radio-frequency Electromagnetic Fields. Equipment should comply with the IEC 801-3 requirements, which are being updated.5 A limit of 3 V/m should be used over a frequency range of 26 MHz to 1 GHz. Other levels apply to equipment used in shielded locations, such as x-ray and MRI facilities. The 3-V/m requirement is decreased in proportion to the increasing shielding effectiveness of the location.

There are provisions for amplitude modulation of the signal, depending upon the passband of the equipment under test (EUT). If the EUT does not have a passband, the signal should be amplitude modulated at 1 kHz.

Bursts. Test methods and instruments specified in IEC 801-4 should be followed.6 A 1-kV level applies to equipment connected to the power line with a plug. For permanently installed equipment, a level of 2 kV applies. Interconnecting lines longer than 3 m should be able to withstand a 0.5-kV surge.

Surges. Test methods and instruments specified in IEC 801-5, which is currently still under consideration, should be followed.7 Power lines should meet levels of 1 kV for differential mode and 2 kV for common mode. Signal lines need not be tested, and telecom lines are covered by other standards. Ring wave and damped sinusoid tests are not applicable.

There are future provisions for voltage dips, short interruptions, and voltage variations on power lines, as well as for conducted immunity above 9 kHz and magnetic field immunity.

Custom Standards

Manufacturers of electrical and electronic equipment for any use are recognizing the need for specifications that ensure compatibility among equipment. Medical electronics manufacturers also recognize that such generic standards are not necessarily appropriate; they may be too severe, or, even worse, not severe enough to protect their products. To lessen confusion and to ensure that test specifications will be appropriate, medical manufacturers should use an existing document such as IEC 60601-1-2 as a basis for creating their own product-specific standards.

References

1."Medical Electrical Equipment Part 1: General Requirements for Safety, Amendment No. 2. Collateral Standard: Electromagnetic Compatibility—Requirements and Tests," Geneva, IEC, Bureau Central de la Commission Electrotechnique, 1st ed, 1993.

2.International Special Committee on Radio Interference, CISPR Publication 11, "Limits and Methods of Measurement of Radio Interference Characteristics of Industrial, Scientific and Medical (ISM) Radio Frequency Equipment (Excluding Surgical Diathermy Apparatus)," Geneva, IEC, 2nd ed, 1990.

3.International Special Committee on Radio Interference, CISPR Publication 14, "Limits and Methods of Measurements of Radio Interference Characteristics of Household Electrical Appliances, Portable Tools and Similar Electrical Apparatus," Geneva, IEC, 2nd ed, 1985.

4.IEC 801-2, "Electromagnetic Compatibility for Industrial-Process Measurement and Control Equipment, Part 2: Electrostatic Discharge Requirements," Geneva, IEC, 2nd ed, 1991.

5.IEC 801-3, "Electromagnetic Compatibility for Industrial-Process Measurement and Control Equipment, Part 3: Radiated Electromagnetic Field Requirements," Geneva, IEC, 1st ed, 1984, 3rd impression, 1991.

6.IEC 801-4, "Electromagnetic Compatibility for Industrial-Process Measurement and Control Equipment, Part 4: Electrical Fast Transient/Burst Requirements," Geneva, IEC, 1st ed, 1988.

7.IEC 801-5, "Electromagnetic Compatibility for Industrial-Process Measurement and Control Equipment, Part 5: Surge Immunity Requirements," draft, Geneva, IEC, July 1992.

TEST REPORT
IEC 60601 -1 Medical electrical equipment Part 1: General requirements for safety

(b)(4) 3rd Party Testing

(b)(4) 3rd Party Testing

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Performance Testing – Bench

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Performance Testing – Animal

19. Performance Testing – Animal

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SUPPLEMENTAL TESTING

(b) (4)

CONCLUSION

The MiSeal device meets all the acceptance criteria of the test protocol as evidenced by the attached final report detailing acceptable test results. The MiSeal device is equivalent to the TLS3 as shown by in vivo and in vitro test results which supports the device equivalency between the MiSeal Reposable Thermal Ligating Shear the subject of this 510(k) submission, and the predicate TLS3 Thermal Ligating Shears.

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Performance Testing – Clinical

20: Performance testing – Clinical

This section is not applicable because a clinical investigation is not required.

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Standards Data Report Forms

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI/ES 60601-1, Medical Electrical Equipment - Part 1:General Requirements for Basic Safety and Essential Performance

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-52	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐
Title of guidance:		

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI/IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: EMC

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-35	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM D4169-01 Standard practice for performing testing of shipping containers and systems

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-300	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ASTM D4169-01 Standard practice for performing testing of shipping containers and systems

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
13	Distribution Cycles	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option DC 13

DESCRIPTION
Air (intercity) and motor freight (local), single package up to 150 lb (61.8 kg).

JUSTIFICATION
Most appropriate for product configuration.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 15223-1:2007 Medical devices-Symbols to be used with medical devices labeling and information Part 1: 2007-01-15

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-59	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☒	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☒
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☒	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☒	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 15223-1:2007 Medical devices-Symbols to be used with medical devices labeling and information Part 1: 2007-01-15

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5.2	Do not re-use	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
option Do not re-use symbol

DESCRIPTION
Do not re-use symbol

JUSTIFICATION
single use device

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5.4	Caution, consult accompanying documents	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option Caution, consult accompanying documents

DESCRIPTION
Caution, consult accompanying documents Symbol

JUSTIFICATION
Required for safe use of the device

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5.14	Batch Code	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option Batch Code

DESCRIPTION
Batch Code symbol

JUSTIFICATION
Class II device requires a lot number

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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Food and Drug Administration
Office of Chief Information Officer
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Rockville, MD 20850

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Standard Title ISO 15223-1:2007 Medical devices-Symbols to be used with medical devices labeling and information Part 1: 2007-01-15		
Section Number 5.15	Section Title Catalog Number	Conformance ☒ Yes ☐ No ☐ N/A
Type of Deviation or Option Selected Option, Symbol "REF"		
Description Serial Number symbol		
Justification Catalog number a requirement of labeling		
Standard Title ISO 15223-1:2007 Medical devices-Symbols to be used with medical devices labeling and information Part 1: 2007-01-15		
Section Number 5.16	Section Title Serial Number	Conformance ☒ Yes ☐ No ☐ N/A
Type of Deviation or Option Selected Option Symbol "SN"		
Description Serial number symbol		
Justification Serial number a requirement of labeling		
Standard Title ISO 15223-1:2007 Medical devices-Symbols to be used with medical devices labeling and information Part 1: 2007-01-15		
Section Number 5.23	Section Title Sterilized using Radiation	Conformance ☒ Yes ☐ No ☐ N/A
Type of Deviation or Option Selected Option Symbol "Sterile R"		
Description Sterile radiation symbol		
Justification Sterile radiation a requirement of labeling		
Standard Title ISO 15223-1:2007 Medical devices-Symbols to be used with medical devices labeling and information Part 1: 2007-01-15		
Section Number 5.25	Section Title Do not resterilize	Conformance ☒ Yes ☐ No ☐ N/A
Type of Deviation or Option Selected Option Symbol "do not resterilize"		
Description Do not resterilize symbol		
Justification Do not resterilize a requirement of labeling		
Standard Title ISO 15223-1:2007 Medical devices-Symbols to be used with medical devices labeling and information Part 1: 2007-01-15		
Section Number N/A	Section Title N/A	Conformance ☐ Yes ☐ No ☒ N/A
Type of Deviation or Option Selected Deviation: "No Latex"		
Description Circle with the word "LATEX" with a line through the circle symbol		
Justification There was no "No Latex" symbol at the release of the labeling. Explained in the Instruction for Use.		

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 11137-1:2006 Sterilization of health care products-Radiation Part 1: requirements for development, validation, an

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☒	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ANSI/AAMI/ISO 11137-1:2006 Sterilization of health care products-Radiation Part 1: requirements for development, validation, an

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8.2	Establishing the Sterilization dose	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option 8.2.8 b)

DESCRIPTION
A sterilization dose of 25kGy is selected and substantiated; in substantiating a sterilization dose of 25 kGy, the primary manufacturer shall have evidence that the selected sterilization dose is capable of achieving the specific requirements for sterility.

JUSTIFICATION
25kGy substantiation is within the validation records

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
N/A	Testing Facility	☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Microbiology Testing Laboratory

DESCRIPTION
Nelson Laboratories, 6280 South Redwood Rd, Salt Lake City, UT 84123-660

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
The Standard referenced in this document is a Relevant Guidance to: AAMI/ANSI ST67:2011, Recognition Number 14-314

DESCRIPTION

JUSTIFICATION

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Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 11137-2:2006 Sterilization of health care products-Radiation Part 2: Establishing the Sterilization dose

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ANSI/AAMI/ISO 11137-2:2006 Sterilization of health care products-Radiation Part 2: Establishing the sterilization dose

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9.2	Procedure for Method VDmax25 for multiple production batches	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Method VDmax25 for multiple production batches

DESCRIPTION
describes the steps and calculations to successfully validate to Method VDmax 25 for gamma irradiation.

JUSTIFICATION
25kGy substantiation is within the validation records

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
N/A	Testing Facility	☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Microbiology Testing Laboratory

DESCRIPTION
Nelson Laboratories, 6280 South Redwood Rd, Salt Lake City, UT 84123-660

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
The Standard referenced in this document is a Relevant Guidance to: AAMI/ANSI ST67:2011, Recognition Number 14-314

DESCRIPTION

JUSTIFICATION

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Department of Health and Human Services
Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 11137-3:2006 Sterilization of health care products-Radiation Part 3: Guidance of dosimetric aspects

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ANSI/AAMI/ISO 11137-3:2006 Sterilization of health care products-Radiation Part 3: Guidance on dosimetric aspects

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Part 3	Guidance on dosimetric aspects	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION
This part of 11137 gives guidance on the requirements in ISO 11137 parts 1 and 2 relating to dosimitry. Dosimitry procedures related to the development, validation and routine control of a radiation sterilization process are described.

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
The Standard referenced in this document is a Relevant Guidance to: AAMI/ANSI ST67:2011, Recognition Number 14-314

DESCRIPTION

JUSTIFICATION

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Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 10993-1:2009 Biological evaluation of medical devices-Part1: Evaluation and testing within a risk management

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 2-156	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F 1980-07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 14-229	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 14971:2007 Medical Devices-Application of risk management to medical devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 5-40	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
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Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: Q9 Quality Risk Mangement

[1] The *formatting convention for the title is: [SDO] [numeric identifier] [title of* standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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