Section 5 510(k) Summary

June 24, 2008

OCT 21 2008

A. Submitter's Name / Address

Ronda K. Magneson
Director, Regulatory Affairs and Quality Assurance
Megadyne Medical Products, Inc.
11506 South State Street
Draper, UT 84020
(801) 576-9669
(801) 576-9698 fax

B. Contact Person

Primary: Ronda K. Magneson
Director of Regulatory Affairs
Megadyne Medical Products, Inc.
11506 South State Street
Draper, UT 84020
(801) 576-9669
(801) 576-9698 fax

Alternate: Ihsan Samara
Quality Manager
Megadyne Medical Products, Inc.
11506 South State Street
Draper, UT 84020
(801) 576-9669
(801) 576-9698 fax

C. Megadyne's Manufacturing Facility

Megadyne Medical Products, Inc.
11506 South State Street
Draper, UT 84020
(801) 576-9669
(801) 576-9698 fax

D. Device Name

Common Name:	Device, electrosurgical, cutting & coagulation & accessories
Trade Name:	E-Z Clean electrosurgical electrodes
Classification (if known):	21 CFR 878.4400, Electrosurgical cutting and coagulation device and accessories

E. Predicate Devices

The predicate devices include American Medical Products' E-Z Clean Cautery Tip which was cleared for marketing via 510(k) # K862221 by FDA's Office of Device Evaluation on August 11, 1986; and Utah Medical Products' Epitome® Scalpel electrode with ZapGuard™ which was cleared for marketing via 510(k) #K960255 on March 27, 1996.

F. Applicant Device Description

The Megadyne E-Z Clean electrosurgical electrode is a monopolar electrosurgical electrode that is coated with polytetrafluoroethylene (PTFE). It is insulated over the majority of its exposed length. It is intended for general electrosurgical use, and is designed to fit into and work in conjunction with an industry standard hand- or foot-activated electrosurgical pencil which is connected to an electrosurgical unit or ESU. This device is supplied sterile and is not intended to be reused.

The E-Z Clean electrosurgical electrodes are available in a number of tip configurations and lengths. Tips such as standard blades, modified blades, needles, blunt needles, ball-ends, and others are typical.

Some tip configurations (ACE blades) contain a slightly different geometry that will enhance the affects of the generator's Advanced Cutting Effect (ACE) Mode. In this mode, the blade will make skin incisions without the blanching or thermal damage commonly seen with standard electrosurgery. The new E-Z Clean ACE Blade provides a wound site that will heal similar to a scalpel wound (comparable Histopathology) when used in conjunction with the ACE mode. When not being used to perform skin incisions the ACE Blade functions as a standard E-Z Clean blade in all cutting and coagulating modes.

This submission also includes the option of a guard or nosecone on some configurations of electrodes. This nose cone provides additional dielectric protection at the junction where the E-Z Clean electrosurgical electrode is connected to an electrosurgical pencil.

G. Applicant Device Intended Use

E-Z Clean electrosurgical electrodes are intended to conduct radio frequency (RF) current for cutting and coagulation from the electrosurgical generator to target soft

tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization.

Some tip configurations have a specific geometry that minimizes blanching and thermal damage in skin incisions when used in conjunction with the generator's Advanced Cutting Effect (ACE) mode.

H. Technological Characteristics

The proposed device shares the same technological characteristics found in the predicate devices. It is an electrosurgical electrode intended for electrosurgical cutting and coagulation.

I. Safety information

Questions of safety and effectiveness are the same for this device as they are for the predicate devices and other electrosurgical electrodes on the market. There are no new technologies incorporated into the device.

Megadyne has conducted extensive testing to ensure conformance to the voluntary standard ISO 60601-2-2:2006, *Medical electrical equipment, Part 2: Particular requirements for the safety of high frequency surgical equipment,* and ANSI / AAMI HF 18-2001, *Electrosurgical Devices.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Megadyne Medical Products, Inc.
% Ms. Ronda K. Magneson
Director, Regualtory Affairs
11506 South State Street
Draper, Utah 84020

OCT 21 2008

Re: K081791
Trade/Device Name: E-Z Clean electrosurgical electrosurgical electrodes
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: October 9, 2008
Received: October 10, 2008

Dear Ms. Magneson:

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

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

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

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

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

Enclosure

Section 4 Indications for Use Statement

510(k) Number (if known): K081791

Device Name: E-Z Clean electrosurgical electrodes

Indications for use:

E-Z Clean electrosurgical electrodes are intended to conduct radio frequency (RF) current for cutting and coagulation from the RF electrosurgical generator to target soft tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization.

Some tip configurations have a specific geometry that minimizes blanching and thermal damage in skin incisions when used in conjunction with the generator's Advanced Cutting Effect (ACE) mode.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K081791

Prescription Use √ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Megadyne Medical Products, Inc.
% Ms. Ronda K. Magneson
Director, Regualtory Affairs
11506 South State Street
Draper, Utah 84020

OCT 21 2008

Re: K081791
Trade/Device Name: E-Z Clean electrosurgical electrosurgical electrodes
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: October 9, 2008
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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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Sincerely yours,

Mark N Melkerson

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

Enclosure

Section 4 Indications for Use Statement

510(k) Number (if known): K081791

Device Name: E-Z Clean electrosurgical electrodes

Indications for use:

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Some tip configurations have a specific geometry that minimizes blanching and thermal damage in skin incisions when used in conjunction with the generator's Advanced Cutting Effect (ACE) mode.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K081791

Prescription Use √ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

September 15, 2008

MEGADYNE MEDICAL PRODUCTS, INC.
11506 SOUTH STATE ST.
DRAPER, UT 84020
ATTN: RONDA K. MAGNESON

510(k) Number: K081791
Product: E-Z CLEAN ELECTROSURGICAL ELECTRODE

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

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

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission. Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-40
9200 Corporate Blvd.
Rockville, Maryland 20850

June 26, 2008

MEGADYNE MEDICAL PRODUCTS, INC.
11506 SOUTH STATE ST.
DRAPER, UT 84020
ATTN: RONDA K. MAGNESON

510(k) Number: K081791
Received: 25-JUN-2008
Product: E-Z CLEAN ELECTROSURGICAL ELECTRODE

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 Federa 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 abov Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you whe 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)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medica device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, th Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/cdrh/mdufma/index.html for more information regardin 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) nee 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/opacom/morechoices/fdaforms/FDA-3654.pdf.

A new provision of the Food and Drug Administration Amendments Act of 2007, 42 U.S.C. 282(j)(5)(B), requires that a certification form (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf) accompany all 510(k)/HDE/PMA submissions on or after December 26, 2007. You are responsible for registering certain device clinical trials in the Clinical Trials Data Bank (http://prsinfo.clinicaltrials.gov). If your submission does not include FDA Form 3674, please send 2 hardcopies of the completed certification form referencing the submission number identified above. Additional information about the new certification

form may be found at the following link to the Federal Register Notice (http://www.fda.gov/OHRMS/DOCKETS/98fr/07-6023.htm).

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/cdrh/ode/guidance/1655.pdf. 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 www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditiona 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 electron copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/" If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/dsmastaf.html. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Heal

45

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

June 25, 2008

MEGADYNE MEDICAL PRODUCTS, INC.
11506 SOUTH STATE ST.
DRAPER, UT 84020
ATTN: RONDA K. MAGNESON

510(k) Number: K081791
Received: 25-JUN-2008
User Fee ID Number: 6037142
Product: E-Z CLEAN ELECTROSURGICAL

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and the FDA Amendments Act of 2007 (FDAAA) (Public Law 110-85), authorizes FDA to collect user fees for certain types of 510(k) submissions. The submission cannot be accepted for review until the fee is paid in full ; therefore, the file has been placed on hold. When your user fee payment has been received , review of the 510(k) will resume as of that date. Alternatively, you may request withdrawal of your submission. Please send a check to one of the addresses listed below:

By Regular Mail	By Private Courier(e.g.,Fed Ex, UPS, etc.)
Food and Drug Administration P.O. Box 956733 St. Louis, MO 63195-6733.	U.S. Bank 956733 1005 Convention Plaza St. Louis, MO 63101 (314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (240)276-4025 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at www.fda.gov/oc/mdufma.

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, or HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (240) 276-3150 or its toll-fee number (800)638-2041, or contact them at their Internet address www.fda.gov/cdrh/dsma/dsmastaf.html, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Christina Zeender at Christina.Zeender@fda.hhs.gov. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

Diane M. Garcia
Public Affairs Specialist
Office of Device Evaluation
Center for Devices and
Radiological Health

MEGADYNE

K081741

510(k) Submission

K24

48

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
6/4/2008	(b) (4)	

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
☐ Supplement	☐ Supplement			*(describe submission):*
	☐ 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)*		
Megadyne Medical Products	1721194		
Division Name *(if applicable)*	Phone Number *(including area code)*		
	(801) 576-9669		
Street Address	FAX Number *(including area code)*		
11506 South State Street	(801) 576-9698		
City	State / Province	ZIP/Postal Code	Country
Draper	UT	84020	USA
Contact Name			
Ronda K. Magneson			
Contact Title	Contact E-mail Address		
Director of Regulatory Affairs	rmagneson@megadyne.com		

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

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

PSC Graphics: (301) 443-2454 EF

49

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

- ☐ 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

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

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

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

- ☐ Response to FDA correspondence:

- ☐ 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

- ☐ Repose 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)*:
  Add the option of EO sterilization
  Add an optional guard or nosecone
  Changes in labeleing related to the use of a specific geometry of electrode in a specific generator CUT mode for skin incisions

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

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

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K862221	1	E-Z Clean Cautery Tip	1	American Medical Products
2	K960255	2	Epitome® Scalpel electrode with ZapGuardTM	2	Utah Medical Products
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Electrosurgical cutting and coagulation device and accessories

	Trade or Proprietary or Model Name for This Device		Model Number
1	E-Z Clean Electrosurgical Electrode	1	TBD
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 ☐ Class III ☐ Unclassified

Classification Panel

GEI-General and Plastic Surgery

Indications *(from labeling)*

E-Z Clean electrosurgical electrodes are intended to conduct radio frequency (RF) current for cutting and coagulation from the RF electrosurgical erator to target tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization.

Some tip configurations have a specific geometry that minimizes blanching and thermal damage in sking incisions when used in conjuction with the generator's Advanced Cutting Effect (ACE) mode.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number *(if known)*

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

Original ☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number: 1721194

☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name: Megadyne Medical Products

Establishment Registration Number: 1721194

Division Name *(if applicable)*

Phone Number *(including area code)*: (801) 576-9669

Street Address: 11506 South State Street

FAX Number *(including area code)*: (801) 576-9698

City: Draper

State / Province: UT

ZIP/Postal Code: 84020

Country: USA

Contact Name: Ronda K. Magneson

Contact Title: Director of Regulatory Affairs

Contact E-mail Address: rmagneson@megadyne.com

☐ Original ☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number

☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name

Establishment Registration Number

Division Name *(if applicable)*

Phone Number *(including area code)*: ( )

Street Address

FAX Number *(including area code)*: ( )

City

State / Province

ZIP/Postal Code

Country

Contact Name

Contact Title

Contact E-mail Address

☐ Original ☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number

☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name

Establishment Registration Number

Division Name *(if applicable)*

Phone Number *(including area code)*: ( )

Street Address

FAX Number *(including area code)*: ( )

City

State / Province

ZIP/Postal Code

Country

ıtact 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	HF-18	AAMI	Electrosurgical Devices	2001	
2	60601-1	IEC	Medical Electrical Equipment- General Requirementsfor basic safety and essential performance	2005	
3	60601-2-2	IEC	Medical Electrical Equipement - Particular Requirements for the safety of high frequency surgical equipement	2006	
4	11135-1	ISO	Sterlization of healthcare products - Ethylene Oxide - Requirements for development, validation, and routing control of a sterlization process for medical devices.	2007	
5	10993	ISO	Biological evaluation of medical devices - Part 1 Evaluation and testing AND Part 7: Ethlyene oxide sterlization residuals	2003 AND 1995	
6	11607	ISO	Packaging for terminally sterlized devices	2006	
7	D4169	ASTM	Standard Practice for Performance Testing of Shipping Containers and Systems	2005	

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:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
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

Table of Contents

SS

Section 1 Medical Device User Fee Cover Sheet (Form FDA 3601)

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b) (4)
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

MEGADYNE MEDICAL PRODUCTS INC
11506 SOUTH STATE STREET
DRAPER UT 84020
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
(b) (4)

2. CONTACT NAME
Ronda Magneson
2.1 E-MAIL ADDRESS
rmagneson@megadyne.com
2.2 TELEPHONE NUMBER (include Area code)
801-5769669-805
2.3 FACSIMILE (FAX) NUMBER (include Area code)
801-5769698

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number: SBD088318

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b) (4)
24-Jun-2008

Form FDA 3601 (01/2007)

Section 2 Screening Checklist for all 510(k) Submissions

510(k) Number: _____

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

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

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

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

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

	Present	Inadequate or Missing
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	Yes (7)	
Table of Contents.	Yes (1)	
Truthful and Accurate Statement.	Yes (14)	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	Yes (8)	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	Yes (8)	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	Yes (29)	
Statement of Indications for Use that is on a separate page in the premarket submission.	Yes (10)	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.	Yes (24)	
510(k) Summary or 510(k) Statement.	Yes (11)	

	Present	Inadequate or Missing
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	Yes (20)	
Identification of legally marketed predicate device.	Yes (19)	
Compliance with performance standards. [See Section 514 of the Act and 21 CFR 807.87 (d).]	Yes (39)	
Class III Certification and Summary.		N/A
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. [See 21 CFR 807.87 (i)]		N/A
510(k) Kit Certification		N/A

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

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

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

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	Yes (36)	
b) Sterilization and expiration dating information:	Yes (35)	
i) sterilization process	Yes (35)	
ii) validation method of sterilization process	Yes (35)	
iii) SAL	Yes (35)	
iv) packaging	Yes (35)	
v) specify pyrogen free		N/A
vi) ETO residues	Yes 35)	
vii) radiation dose	Yes (35	

	Present	Inadequate or Missing
c) Software Documentation:		N/A

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

Passed Screening _____Yes _____No

Reviewer:_____

Concurrence by Review Branch:_____

Date:_____

Section 3 Cover Letter

June 24, 2008

Food and Drug Administration
Center for Devices and Radiological Health
510 (K) Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 50208

JUL RECD

Attention: Document Control Clerk

RE: 510(k) Notification

Megadyne Medical Products, Inc. hereby notifies the Food and Drug Administration of its intent to market the device described below. This device is not exempt from 510(k) by regulation or policy. It is subject to review by CDRH.

This 510(k) includes all of the information needed to process this Traditional 510(k) application according to 21 CFR 807.87, the "checklist" under the refuse-to-accept policy, and other guidance documents known at the time of submission. Please refer to the table of contents for a listing of the information included in this 510(k) and its location. The basis of this submission is a modification of a legally marketed device that would not otherwise qualify for a Special 510(k).

Please note that Megadyne's intent with this submission is to include all E-Z Clean Electrosurgical Electrodes (excluding laparoscopic) and thereby update the original 510(k) submission to current configurations. The design changes to this family of products that require 510(k) notification include:

- option of EO sterilization
- addition of an optional guard or nosecone
- changes to Labeling regarding use of the E-Z Clean ACE blade for skin incisions

In addition, various insignificant changes to the product specifications and labeling are included in the information provided for this review but do not influence equivalency.

The following list of information is intended to assist the initial reviewer in routing and for compliance to 21 CFR 807.87.

Submitter's Name / Address	Ronda K. Magneson Director, Regulatory Affairs Megadyne Medical Products, Inc. 11506 South State Street Draper, UT 84020 (801) 576-9669 (801) 576-9698 fax
Primary Contact:	Same as above
Alternate Contact:	Ihsan Samara Manager, Quality Assurance Megadyne Medical Products, Inc. 11506 South State Street Draper, UT 84020 (801) 576-9669 (801) 576-9698 fax
Device Name (Common Name):	Device, electrosurgical, cutting & coagulation & accessories
Device Name (Proprietary Name):	E-Z Clean electrosurgical electrodes
Classification Name:	21 CFR 878.4400 Electrosurgical cutting and coagulation device and accessories
Classification Panel:	GEI, General and Plastic Surgery
Class:	2
Tier:	II
Establishment Registration Number:	1721194
Performance Standards:	None established under section 514 of the Federal Food, Drug, and Cosmetic Act. ANSI / AAMI HF 18-2001 and IEC 60601-2-2:2006 are voluntary performance standards for electrosurgical devices.

Substantial Equivalence:

These electrosurgical electrodes are substantially equivalent to American Medical Products' E-Z Clean Cautery Tip 510(k) # K862221, and Utah Medical Products' Epitome® Scalpel electrode with ZapGuard™ 510(k) #K960255. (See the Section 12 entitled "Substantial Equivalence Discussion")

The following table addresses the principal factors about the 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?	√	
Is the device intended for single use?	√	
Is the device a reprocessed single use device?		√
If yes, does this device type require reprocessed validation data?	N/A	
Does the device contain a drug?		√
Does the device contain a biologic?		√
Does the device use software?		√
Does the submission include clinical information?		√
Is the device implanted?		√

The subject of this 510(k) application is a low-risk device that is substantially equivalent to the predicate devices listed and there are no significant questions of safety and efficacy. We hope that you will concur with this conclusion and speedily return a substantially equivalent decision.

Best Regards,

Ronda K. Magneson

Ronda K. Magneson
Director, Regulatory Affairs

Section 4 Indications for Use Statement

510(k) Number (if known): _____

Device Name: E-Z Clean electrosurgical electrodes

Indications for use:

E-Z Clean electrosurgical electrodes are intended to conduct radio frequency (RF) current for cutting and coagulation from the RF electrosurgical generator to target tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization.

Some tip configurations have a specific geometry that minimizes blanching and thermal damage in skin incisions when used in conjunction with the generator's Advanced Cutting Effect (ACE) mode.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

Section 5 510(k) Summary

June 24, 2008

A. Submitter's Name / Address

Ronda K. Magneson
Director, Regulatory Affairs and Quality Assurance
Megadyne Medical Products, Inc.
11506 South State Street
Draper, UT 84020
(801) 576-9669
(801) 576-9698 fax

B. Contact Person

Primary: Ronda K. Magneson
Director of Regulatory Affairs
Megadyne Medical Products, Inc.
11506 South State Street
Draper, UT 84020
(801) 576-9669
(801) 576-9698 fax

Alternate: Ihsan Samara
Quality Manager
Megadyne Medical Products, Inc.
11506 South State Street
Draper, UT 84020
(801) 576-9669
(801) 576-9698 fax

C. Megadyne's Manufacturing Facility

Megadyne Medical Products, Inc.
11506 South State Street
Draper, UT 84020
(801) 576-9669
(801) 576-9698 fax

D. Device Name

Common Name:	Device, electrosurgical, cutting & coagulation & accessories
Trade Name:	E-Z Clean electrosurgical electrodes
Classification (if known):	21 CFR 878.4400, Electrosurgical cutting and coagulation device and accessories

E. Predicate Devices

The predicate devices include American Medical Products' E-Z Clean Cautery Tip which was cleared for marketing via 510(k) # K862221 by FDA's Office of Device Evaluation on August 11, 1986; and Utah Medical Products' Epitome® Scalpel electrode with ZapGuard™ which was cleared for marketing via 510(k) #K960255 on March 27, 1996.

F. Applicant Device Description

The Megadyne E-Z Clean electrosurgical electrode is a monopolar electrosurgical electrode that is coated with polytetrafluoroethylene (PTFE). It is insulated over the majority of its exposed length. It is intended for general electrosurgical use, and is designed to fit into and work in conjunction with an industry standard hand- or foot-activated electrosurgical pencil which is connected to an electrosurgical unit or ESU. This device is supplied sterile and is not intended to be reused.

The E-Z Clean electrosurgical electrodes are available in a number of tip configurations and lengths. Tips such as standard blades, modified blades, needles, blunt needles, ball-ends, and others are typical.

Some tip configurations (ACE blades) contain a slightly different geometry that will enhance the affects of the generator's Advanced Cutting Effect (ACE) Mode. In this mode, the blade will make skin incisions without the blanching or thermal damage commonly seen with standard electrosurgery. The new E-Z Clean ACE Blade provides a wound site that will heal similar to a scalpel wound (comparable Histopathology) when used in conjunction with the ACE mode. When not being used to perform skin incisions the ACE Blade functions as a standard E-Z Clean blade in all cutting and coagulating modes.

This submission also includes the option of a guard or nosecone on some configurations of electrodes. This nose cone provides additional dielectric protection at the junction where the E-Z Clean electrosurgical electrode is connected to an electrosurgical pencil.

G. Applicant Device Intended Use

E-Z Clean electrosurgical electrodes are intended to conduct radio frequency (RF) current for cutting and coagulation from the electrosurgical generator to target tissue

in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization.

Some tip configurations have a specific geometry that minimizes blanching and thermal damage in skin incisions when used in conjunction with the generator's Advanced Cutting Effect (ACE) mode.

H. Technological Characteristics

The proposed device shares the same technological characteristics found in the predicate devices. It is an electrosurgical electrode intended for electrosurgical cutting and coagulation.

I. Safety information

Questions of safety and effectiveness are the same for this device as they are for the predicate devices and other electrosurgical electrodes on the market. There are no new technologies incorporated into the device.

Megadyne has conducted extensive testing to ensure conformance to the voluntary standard ISO 60601-2-2:2006, *Medical electrical equipment, Part 2: Particular requirements for the safety of high frequency surgical equipment,* and ANSI / AAMI HF 18-2001, *Electrosurgical Devices.*

Section 6 Premarket Notification Truthful and Accurate Statement

[As required by 21 CFR 807.87(j)]

I certify that, in my capacity as the Director of Regulatory Affairs of Megadyne Medical Products, 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.

Ronda K. Magneson

(Signature)

Ronda K. Magneson

(Typed Name)

24 Jun 2008

(Dated)

I certify that, in my capacity as the V.P. of Engineering, Megadyne Medical Products, 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.

(Signature)

Thomas F. Aramayo

(Typed Name)

6.24.2008

(Dated)

(Premarket Notification [510(k)] Number)

Section 7 Class III Summary and Certification

This section does not apply. The proposed device is Class II.

Section 8 Financial Certification or Disclosure Statement

This section does not apply. This submission does not include information from clinical studies. Form 3674 is included in Appendix D.

Section 9 Declaration of Conformity

Megadyne Medical Products, Inc. (Megadyne) declares that the E-Z Clean electrosurgical electrode conforms to the relevant provisions of the following standards and is in accordance with Megadyne's Quality Management System as verified by internal and external testing:

ANSI / AAMI HF 18:2001, *Electrosurgical Devices*

IEC 60601-1-1:2000, *Medical Electrical Equipment – Part 1: General Requirements for Safety*

IEC 60601-2-2:2006, *Medical Electrical Equipment – Part 2: Particular Requirements for the Safety of High Frequency Surgical Equipment*

ISO 10993-1:2003, *Biological Evaluation of medical devices – Part 1: Evaluation and Testing*

ISO 10993-7:1995, *Biological Evaluation of Medical Devices – Part 7 Ethylene Oxide Sterilization Residuals*

ISO 11135-1:2007, *Sterilization of healthcare products - Ethylene Oxide – Requirements for development, validation and routing control of a sterilization process for medical devices*

ISO 11607-1:2006, *Packaging for terminally sterilized devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2:2006, *Packaging for terminally sterilized devices – Part 2: Validation Requirements for forming, sealing, and assembly processes*

ASTM D4169:2005, *Standard Practice for Performance Testing of Shipping Containers and Systems*

This document certifies that Megadyne has completed extensive testing to assure product conformance to these voluntary standards. Conformance with the requirements of the above standards has been demonstrated using the methods specified by the standard, as they apply to accessories as defined on FDA Form 3654, located in Appendix C of this submission.

Signed:

Kenda K. Magneson
Director, Regulatory Affairs

2015 Jun 24
Date

Vice President, Engineering

6.24.2002
Date

Section 10 Executive Summary

In the U.S. there are approximately 36 million surgical procedures performed each year, 85% (30 Million) of which use electrosurgery to cut and coagulate tissue. Monopolar electrosurgery is the most popular method of electrosurgery because it allows the surgeon to both cut and coagulate tissue. In the monopolar mode current passes from the active electrode through the patient's body to the patient return electrode and back to the generator to complete the circuit. For an electrosurgical effect to occur current must flow. Therefore current must flow from the generator to the patient and back to the generator. A break in the circuit will not allow current to flow.

Cutting and coagulation is affected by the active electrosurgical electrode due to the very high energy densities at the tip. Burns do not occur at the patient return electrode site because the energy is dispersed over a sufficient area to prevent a significant build-up of heat under the pad.

Electrosurgical pencils, hand- or foot- activated devices, are routinely used in the operating room to deliver radio frequency current from the generator to the surgical site. Most electrosurgery is accomplished using blade electrodes.

When the "CUT" switch is activated, a lower voltage, pure sine wave current is delivered to the surgical site to affect the cutting of tissue. The continuous delivery of the current causes the cells to heat, burst, and separate. As a result, the target tissue is cut with no hemostasis.

When the "COAG" switch is activated, higher voltages in an interrupted waveform are delivered through the pencil. This causes the tissue cells to heat and dehydrate, not burst. By dehydrating the cells, a coagulum is formed which creates hemostasis.

More than 20 years ago Megadyne (formerly American Medical Products) developed the E-Z Clean line of electrodes, or cautery tips (K862221). E-Z Clean non-stick cautery tips are coated with a PTFE coating that reduces eschar build up and allows for cleaner, safer electrosurgery.

In more recent years, Megadyne introduced to the market a high quality, innovative yet easy to use electrosurgical generator (K050579). One differentiating feature of Megadyne's MEGA Power electrosurgical generator is the ACE Mode (Advanced Cutting Effect). The ACE Mode is a derivative of a cut mode in the electrosurgical generator. The ACE Mode delivers a specially designed waveform to fully emulate the cutting effect of a surgical scalpel (no hemostasis).

The proposed device includes some tip configurations with a specific geometry to enhance the effects of the ACE mode without causing the blanching and thermal damage typically seen with use of standard electrosurgical electrodes when making skin incisions. When not being used to perform skin incisions, the ACE Blade will function as a standard E-Z Clean electrosurgical electrode in all cutting and coagulating modes.

Use of the E-Z Clean ACE Blade and ACE mode to perform skin incisions will provide clinicians with a safer environment in which to work as sharp scalpels are removed from the procedure.

A. Predicate Devices

The predicate devices include American Medical Products' E-Z Clean Cautery Tip which was cleared for marketing via 510(k) # K862221 by FDA's Office of Device Evaluation on August 11, 1986; and Utah Medical Products' Epitome® Scalpel electrode with ZapGuard™ which was cleared for marketing via 510(k) #K960255 on March 27, 1996.

B. Proposed Device

The proposed device is identical in device operating principle and intended use. It also shares similarities in design, materials and construction.

A device comparison table outlining the differences and similarities between the proposed device and the predicates is provided in Section 12, Substantial Equivalence Discussion.

The applicant device is a low-risk device that is substantially equivalent to the predicate devices listed and there are no significant questions of safety and efficacy.

Section 11 Device Description

(See Figures A, B, and C below)

The Megadyne E-Z Clean electrosurgical electrode is a monopolar electrosurgical electrode that is coated with polytetrafluoroethylene (PTFE). It is insulated over the majority of its exposed length. It is intended for general electrosurgical use, and is designed to fit into and work in conjunction with an industry standard hand- or foot-activated electrosurgical pencil which is connected to an electrosurgical generator or ESU.

(See Figure A below) The device consists of a formed stainless steel rod (1) that is coated with PTFE at the distal end (2) and insulated over most of its length with polyolefin insulation (3). The flat, or blade, end of the electrode conducts the energy from a standard high-frequency electrosurgical generator to the target tissue. Modified configurations also include an extension of PTFE insulation that surrounds all but the distal 3-5 mm of the electrode tip (4) focusing the current and minimizing the likelihood of damage to surrounding tissues. The proximal end fits into a standard electrosurgical handpiece.

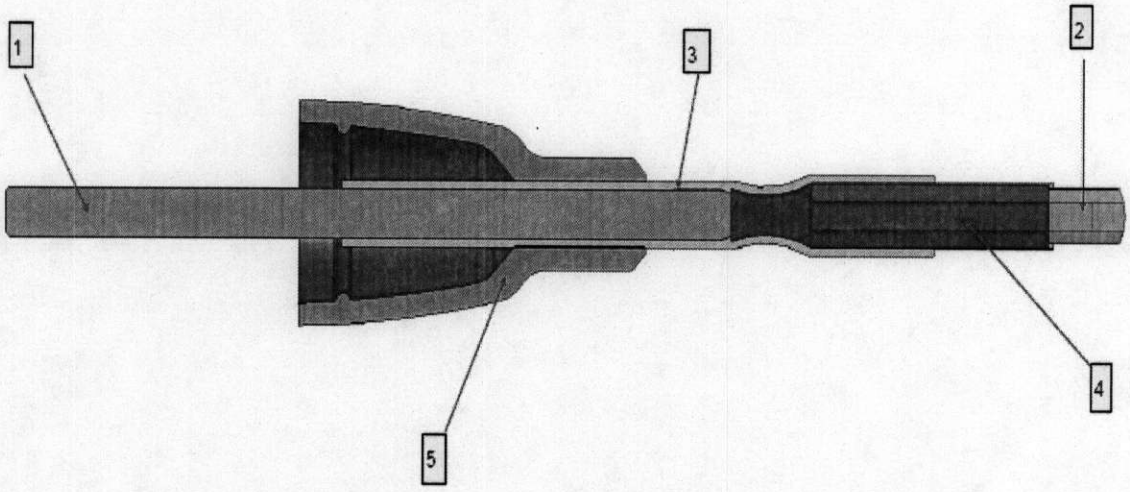


Figure A

The E-Z Clean electrosurgical electrodes are available in a number of tip configurations and lengths. Tips such as standard blades, modified blades, needles, blunt needles, ball-ends, and others are typical.

This submission also includes the option of a guard or nosecone on some configurations of blades (5). This nose cone provides additional dielectric protection at the junction

where the E-Z Clean electrosurgical electrode is connected to an electrosurgical pencil. (See Figure B below)

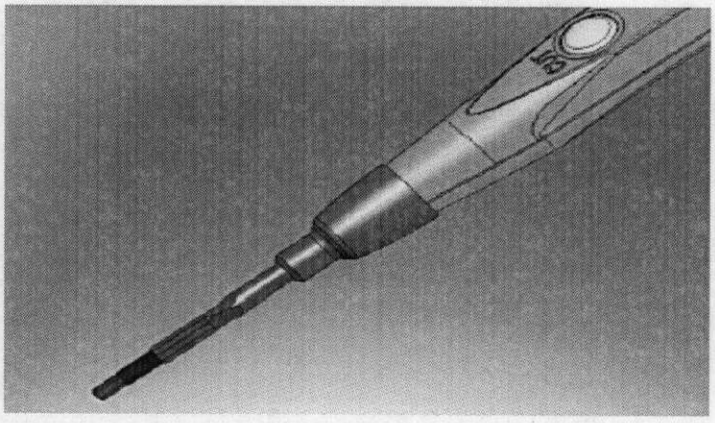


Figure B

Some tip configurations (see Figure C below) contain a slightly different geometry that involves a thinning of the blade towards the outer edges that will enhance the effects of the ACE Mode (reference 510k #K050579). In this mode, the new tip geometry of the E-Z Clean electrode (ACE Blade) will make skin incisions without the blanching or thermal damage commonly seen with standard electrosurgery.

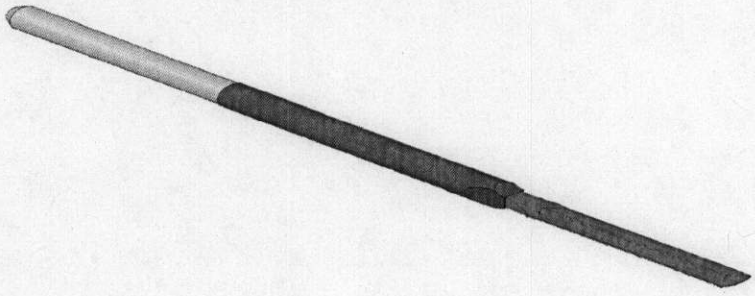


Figure C

This new geometry will provide a wound site that heals similar to a scalpel wound, i.e. comparable Histopathology (see test report), when used in conjunction with the ACE mode. When not being used to perform skin incisions, the ACE Blade will function as a standard E-Z Clean electrosurgical electrode in all cutting and coagulating modes.

Typical lengths and tip configurations include:

Catalog Number	*Description*
0009	E-Z Clean ball electrode, 5"
0012	E-Z Clean flat blade electrode, 2.5"
0012A	E-Z Clean flat blade electrode, 2.75"
0012AM	E-Z Clean flat blade electrode, 2.75", modified
0012M	E-Z Clean flat blade electrode, 2.5", modified

Catalog Number	*Description*
ACE 0012	ACE flat blade electrode, 2.5"
ACE 0012A	ACE flat blade electrode, 2.75"
0012AMD	E-Z Clean flat blade electrode, 2.75", modified, with nose cone
0012MD	E-Z Clean flat blade electrode, 2.5", modified, with nose cone
0013	E-Z Clean needle electrode, 2.75"
0013M	E-Z Clean needle electrode, 2.75", modified
0013MD	E-Z Clean needle electrode, 2.75", modified, with nose cone
0014	E-Z Clean flat blade electrode, 6.5"
0014A	E-Z Clean flat blade electrode, 4"
0014AM	E-Z Clean flat blade electrode, 4", modified
0014M	E-Z Clean flat blade electrode, 6.5", modified
0014AMD	E-Z Clean flat blade electrode, 4", modified, with nose cone
0014MD	E-Z Clean flat blade electrode, 6.5", modified, with nose cone
0015	E-Z Clean ball electrode, 2"
0016	E-Z Clean needle electrode, 6"
0016A	E-Z Clean needle electrode, 4", step-down
0016AM	E-Z Clean needle electrode, 4", step-down, modified
0016M	E-Z Clean needle electrode, 6", modified
0028	E-Z Clean needle electrode, 5.75", bayonet
0028M	E-Z Clean needle electrode, 5.75", bayonet, modified
0029	E-Z Clean Flat Blade electrode, 6.25", bayonet
0029M	E-Z Clean Flat Blade electrode, 6.25", bayonet, modified
0066	E-Z Clean flat blade electrode, 2.5", All-in-One
0113A	E-Z Clean needle electrode, 4.5", blunt needle
C117	E-Z Clean flat blade electrode, 12cm
C117M	E-Z Clean flat blade electrode, 12cm, modified
0118	E-Z Clean, Sharp Needle, 2"
0118A	E-Z Clean, Sharp Needle, 2.5"
0113	E-Z Clean, Blunt Needle, 2.75"
0113M	E-Z Clean, Blunt Needle, 2.75", modified
0119	E-Z Clean MEGAfine 45 degree Needle
0119A	E-Z Clean MEGAfine 45 degree Needle, 3mm
0120	E-Z Clean MEGAfine 90 degree Needle
0121	E-Z Clean MEGAfine Needle Electrode, 6.5"

Sample drawings of the proposed device, including packaging configuration, are provided in Appendix A of this submission.

A. Device Intended Use

E-Z Clean electrosurgical electrodes are intended to conduct radio frequency (RF) current for cutting and coagulation from the electrosurgical generator to target tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization. The device is intended for single use; it is not intended to be cleaned or reused.

Some tip configurations have a specific geometry that minimizes blanching and thermal damage in skin incisions when used in conjunction with the generator's Advanced Cutting Effect (ACE) mode.

B. Discussion of device installation

In use, this device is inserted into a hand- or foot-activated electrosurgical pencil that is connected to an electrosurgical generator. Megadyne recommends in the Instructions for Use that users familiarize themselves with the performance of the ACE Blade and ACE mode combination by practicing their technique on appropriate tissue simulations to determine the anticipated scalpel-like cutting characteristics.

C. Discussion of device operating principle

E-Z Clean electrosurgical electrodes are accessory devices to electrosurgical generators. They are intended to conduct radio frequency (RF) current for cutting and coagulation from the electrosurgical generator to target tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization. The non-stick coating reduces eschar build up and allows for cleaner, safer electrosurgery.

The optional guard or nosecone provides an additional dielectric insulating layer to protect the user and patient from shock or burn due to unintentional direct or indirect contact with the joint between the electrode and the handpiece.

The cut mode in electrosurgery uses lower voltages and sends a pure sine waveform to affect the cutting or tissue. The continuous uninterrupted delivery of the current causes the cells to heat, burst and separate with no hemostasis. The ACE mode is a "CUT" mode derivative. The ACE Blade provides a unique tissue dispersive geometry that will work in conjunction with the aforementioned ACE Mode insomuch that this matched combination will generate a clinical effect of making skin incisions with minimal to no blanching or thermal damage, thus emulating a cold scalpel.

This new geometry will provide a wound site that heals similar to a scalpel wound, i.e. comparable Histopathology (see test report), when used in conjunction with the ACE mode. When not being used to perform skin incisions, the ACE Blade will function as a standard E-Z Clean electrosurgical electrode in all cutting and coagulating modes. In addition, the clinician will have a safer environment in which to work as sharp scalpels will be removed from the procedure.

Section 12 Substantial Equivalence Discussion

This device is substantially equivalent to the American Medical Products' E-Z Clean Cautery Tip (K862221) and Utah Medical Products' Epitome® Scalpel electrode with ZapGuard™ (K960255). Listed below is a comparison of the features of the proposed device and the predicate devices.

A. Comparison table of the proposed device and the predicate devices

Component/ Feature	Proposed Device	Predicate Device: E-Z Clean Cautery Tip (K862221)	Predicate Device: Epitome with ZapGuard (K960255)
Intended use	to be used in any application which requires electrosurgical cutting or coagulation	same	same
Electrode Material	300 series stainless steel	same	Stainless Steel, Ceramic, and tungsten wire
Insulation Material	Polyolefin and PTFE	Polyolefin	Polyolefin
Coating Material	PTFE	PTFE	none
Guard Material	Silicone	none	Silicone
Configurations available	Various including blade, needle, and ball end electrodes	same	Blade
Sterilization	Radiation – Gamma EO	Radiation - Gamma	EO
Compatibility	Standard 3/32" shaft	same	same
Single use	yes	same	same
Conforms with IEC 60601-2-2	yes	same	same

B. Discussion of similarities

The proposed device is similar to the predicate devices in configuration, intended use, technology, performance, and operation principle.

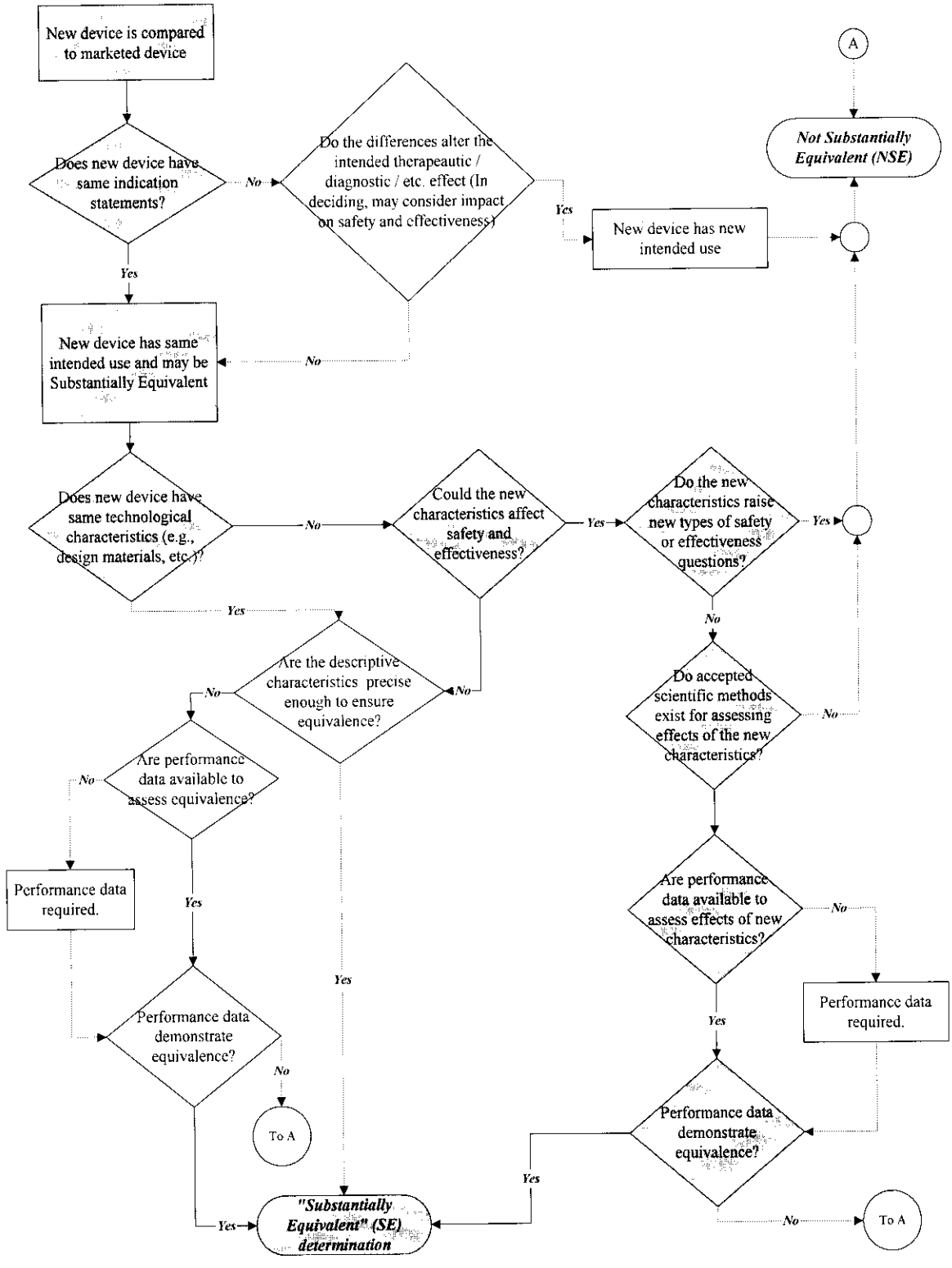
C. Discussion of differences

The only difference as identified in the table above is the insulating material used on certain configurations of the Megadyne electrode is a combination of polyolefin and PTFE, whereas the material used on the predicate device is polyolefin. The PTFE material was selected for some modified configurations as a more durable material than polyolefin.

The addition of PTFE insulation is an insignificant change that does not require the submission of a new 510(k) according to the FDA guidance document *Deciding When to Submit a 510(k) for a Change to an Existing Device*, dated January 10, 1997, since the material is biocompatible, and provides sufficient insulation strength to meet the requirements of ANSI / AAMI HF18-2001.

D. Substantial Equivalence Decision-Making Process Flowchart

The 510(k) Substantial Equivalence Decision-Making Process Flowchart used by ODE in evaluating 510(k) notifications follows, with the applicable decision points highlighted in gray and explained in the table following the chart.



Decision-Making Process Flowchart step	Answer	Remarks
New Device Is Compared To Predicate Device	Yes	The proposed device is substantially equivalent to Megadyne Medical Products' E-Z Clean Cautery Tip (K862221) and Utah Medical Products' Epitome® Scalpel electrode with ZapGuard™ (K960255).
Does New Device Have Same Indication Statements?	Yes	The new device has the same indication statement as the predicate device. Ref. "Indication for Use" statement, Section 4.
New Device Has Same Indication Statements And May Be "Substantially Equivalent"		
Does New Device Have Same Technological Characteristics (e.g., Design, Materials, Etc.)?	No	The proposed device shares the same technological characteristics found in the predicate devices but utilizes different materials. Ref. Section 12, Substantial Equivalence Discussion.
Could The New Characteristics Affect Safety Or Effectiveness?	Yes	The changes which are the subject of this 510(k) involve material changes. Those changes require examination of the impact, if any, on the device safety or effectiveness.
Do the characteristics raise new types of safety or effectiveness questions?	No	The differences are discussed in Section 12 entitled "Substantial Equivalence Comparison". The differences do not raise any new types of safety or effectiveness questions.
Do accepted scientific methods exist for assessing effects of the new characteristics?	Yes	Industry Standards exist and testing of the proposed device ensures conformance with these standards. Ref. Sections 9, Declaration of Conformance and Section18, Performance Testing.

Decision-Making Process Flowchart step	Answer	Remarks
Are performance data available to assess effects of new characteristics?	Yes	Megadyne certifies that performance data is available and the device conforms to the applicable standards. Ref. Section 9, Declarations of Conformance, Section 15, Biocompatability, and Section 18, Performance Testing - Bench.
Performance Data Demonstrate Equivalence?	Yes	Performance data demonstrates substantial equivalence. The changes do not affect the safety and effectiveness of the device. Ref. Section 9, Declarations of Conformance, Section 15, Biocompatability, and Section 18, Performance Testing - Bench..
"Substantially Equivalent" Determination		The device is substantially equivalent to the predicate device.

Section 13 Proposed Labeling

Labeling for the E-Z Clean electrosurgical electrodes consists of the pouch label, box label, and the accompanying Instructions for Use (IFU). Advertising literature is undetermined at this point. All labels will be developed in accordance with Megadyne's standard label control and approval procedures.

Examples of the proposed device draft labeling follow in this section. A sample of the predicate device IFUs are provided in Appendix B.

A. Box Labels

Figure D below illustrates the box label for devices that are sterilized by exposure to Gamma radiation.

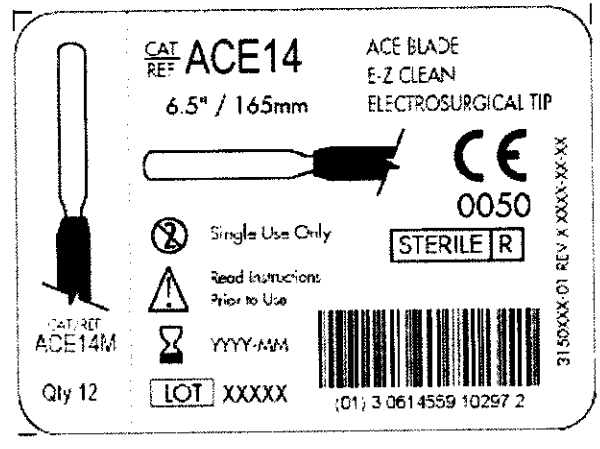


Figure D

Figure E below illustrates the box label for devices that are sterilized by exposure to Ethylene Oxide.

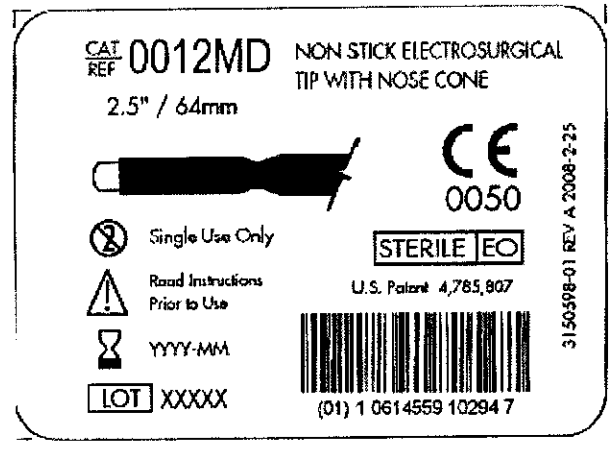


Figure E

B. Unit Labels

Figure F below illustrates a typical unit label for devices that are sterilized by exposure to Gamma radiation.

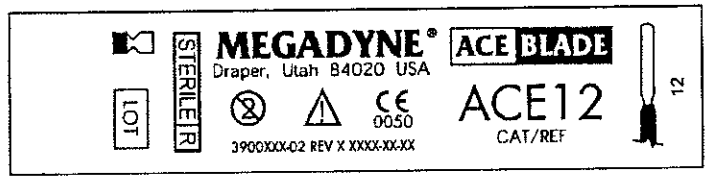


Figure F

Figure G below illustrates a typical unit label for devices that are sterilized by exposure to Ethylene Oxide.

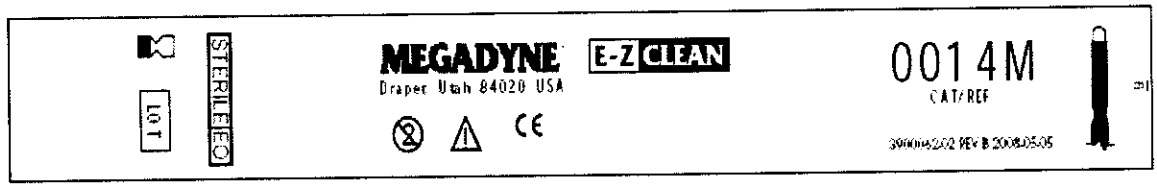


Figure G

C. Device Instructions for Use

The following illustrates the Instructions for Use for the E-Z Clean electrosurgical electrodes with and without the nose cone.

MEGADYNE®
11506 SOUTH STATE STREET
DRAPER, UTAH 84020 USA
Phone: +1 (801) 576-9669 +1 (800) 747-6110 (USA)
Fax: +1 (801) 576-9698 +1 (888) 747-8774 (USA)

E-Z CLEAN Electrosurgical Electrodes

E-Z CLEAN electrosurgical electrodes are intended to conduct radio frequency (RF) current for cutting and coagulation from the RF electrosurgical generator to target tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization.

INSTRUCTIONS FOR USE

E-Z CLEAN electrosurgical electrodes are coated with PTFE to reduce eschar buildup and aid in the easy removal of eschar with a damp gauze or sponge.

E-Z CLEAN electrosurgical electrodes are designed to fit most electrosurgical pencils and other electrosurgical accessories. Prior to use, ensure the electrode has the proper compatibility and fit with the accessory.

To place the E-Z CLEAN Electrosurgical electrodes into an electrosurgical accessory:

1. Ensure the accessory is not connected to the generator.
2. Fully insert the electrode into the accessory. Make sure the insulating sleeve fits securely inside the accessory. If the electrode is equipped with a protective nose cone make sure the electrode fully seats in the pencil.
3. If the insulating sleeve does not fit securely inside the accessory, do not use the electrode.
4. Some electrodes are supplied with a tip protector. If a tip protector is present, remove prior to use.

WARNINGS

- **When not in use, store active electrodes in an electrically insulated container.**
- **If the E-Z CLEAN electrosurgical electrode is equipped with a protective nosecone. Do not remove the nosecone.**
- **Electrosurgical electrodes that are activated or hot from use can cause a fire; do not place them near or in contact with flammable materials and substances (e.g. drapes, flammable gases, endotracheal tubes, etc).**
- **Electrosurgery should not be used to perform circumcisions.**
- **Use the lowest possible power settings to achieve the desired effect.**

CAUTIONS

- **These devices are intended for single use only. Properly discard after use. Do not resterilize.**
- **E-Z CLEAN blade electrodes can be bent up to approximately 60°. The use of instruments to modify the electrode and / or excessive bending may damage the coating or the electrode.**
- **Do not use a scratch pad or other abrasive cleaner to remove eschar. This may damage the PTFE coating.**
- **If the electrode or coating is damaged discard the electrode.**
- **Refer to the generator manufacturer's operating manual for proper usage of electrosurgical generator(s).**

- **Activate electrodes when in contact, or in close proximity to target tissue to avoid the possibility of unintended tissue damage.**
- **Federal (USA) law restricts this device to sale by or on the order of a physician.**

STERILE EO R

Do Not Use If Package Is Damaged

Latex Free

CE
0050

Below illustrates the Instructions for Use for the ACE Blade electrosurgical electrode:

MEGADYNE®
11506 SOUTH STATE STREET
DRAPER, UTAH 84020 USA
Phone: +1 (801) 576-9669 +1 (800) 747-6110 (USA)
Fax: +1 (801) 576-9698 +1 (888) 747-8774 (USA)

ACE BLADE Electrosurgical Tips

E-Z Clean electrosurgical electrodes are intended to conduct radio frequency (RF) current for cutting and coagulation from the RF electrosurgical generator to target tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization.

Some tip configurations have a specific geometry that minimizes blanching and thermal damage in skin incisions when used in conjunction with the generator's Advanced Cutting Effect (ACE) mode.

Megadyne recommends clinicians familiarize themselves with the performance of the ACE Blade and ACE mode combination by practicing their technique on appropriate tissue simulations to determine the anticipated scalpel-like cutting characteristics.

INSTRUCTIONS FOR USE

1. The ACE blade in ACE Mode can be used at any stage of a surgical procedure to dissect tissue where little to no thermal damage is desired. The ACE blade can be

used as a standard electrosurgical blade in coagulate modes or blended modes during the procedure, alleviating the need to change electrosurgical blades.

2. ACE BLADE Electrosurgical tips are coated with PTFE to reduce eschar buildup and aid the easy removal of eschar with a damp gauze or sponge
3. ACE BLADE Electrosurgical tips are designed to fit most electrosurgical pencils and other electrosurgical accessories. Prior to use, ensure the electrode has the proper compatibility and fit with the accessory.
4. To use ACE Blade for scalpel-like effect, place generator in ACE Mode.
5. Incisions may be made using a single pass technique or multiple passes.
6. Cutting with the ACE blade requires very little downward pressure to penetrate the skin and relatively little pressure when compared to a cold scalpel.
7. Each pass should be made using a determined stroke not pausing at any point in the course of the incision. Moving slowly through the tissue does not increase the cutting ability of the ACE blade and may cause thermal damage.
8. For skin incisions, prior to making contact activate the ACE Mode by pressing the yellow cut button on the pencil.

To place the ACE BLADE Electrosurgical tips into an electrosurgical accessory:

1. Ensure the accessory is not connected to the generator.
2. Fully insert the electrode into the accessory. Make sure the insulating sleeve fits securely inside the accessory.
3. If the insulating sleeve does not fit securely inside the accessory, do not use the electrode.
4. Some electrodes are supplied with a tip protector. If a tip protector is present, remove prior to use.

WARNINGS

- **When not in use, store active electrodes in an electrically insulated container.**
- **Electrosurgical tips that are activated or hot from use can cause a fire; do not place them near or in contact with flammable materials and substances (e.g. drapes, flammable gases, endotracheal tubes, etc).**
- **Electrosurgery should not be used to perform circumcisions.**
- **Use the lowest possible power settings to achieve the desired effect.**

CAUTIONS

- **These devices are intended for single use only. Properly discard after use. Do not resterilize.**

- **ACE BLADE Electrosurgical tips can be bent up to approximately 60°. The use of instruments to modify the electrode and / or excessive bending may damage the coating or the electrode.**
- **Do not use a scratch pad or other abrasive cleaner to remove eschar. This may damage the PTFE coating.**
- **If the electrode or coating is damaged discard the electrode.**
- **Refer to the generator manufacturer's operating manual for proper usage of electrosurgical generator(s).**
- **For non-skin incisions, activate the electrodes when in contact, or in close proximity to target tissue to avoid the possibility of unintended tissue damage.**
- **Moving slowly through the tissue does not increase the cutting ability of the ACE blade and may deliver excessive energy to surrounding tissues causing unwanted thermal damage to the incision edges.**

- Federal (USA) law restricts this device to sale by or on the order of a physician.

87

Section 14 Sterilization and Shelf Life

The proposed device will be supplied sterile with the option of being sterilized by either of two traditional sterilization methods. The most commonly used method will be exposure to Co-60 radiation, in accordance with ISO 11137-1 *Sterilization of health care products – Requirements for validation and routine control - Radiation sterilization*, and AAMI/TIR 33, *Radiation Sterilization-Substantiation of 25 kGy as a Sterilization Dose-Method VD Max.* The product is validated to a Sterility Assurance Level (SAL) of 10-6. the minimum dose for achieving this SAL is 25 kGy.

The modified configurations, with the PTFE insulation addition, will be sterilized by exposure to 100% Ethylene Oxide in accordance with ISO 11135-1 *Sterilization of health care products – Ethylene oxide – Requirements for development, validation and routine control of a sterilization process for medical devices,* and ISO 10993-7 *Biological Evaluation of Medical Devices – Part 7 Ethylene Oxide Sterilization Residuals.* This product will be validated to a Sterility Assurance Level (SAL) of 10^{-6} using the following cycle that will be validated with a minimum of four half cycles and three full cycles:

24 hours preconditioning at 110 ±10°F

Three Nitrogen washes
Chamber Temperature 120 °F
Vacuum Level 2.0 inHg
Steam Addition 1.5 inHg
Gas Injection 11.0 inHg
Full cycle Gas Dwell 3 hours

Aeration for 24 hours
Maximum residual level of EO 20mg
Maximum residual level of ECH 12mg

The E-Z Clean electrodes will be packaged in a Tyvek® - polyester chevron peel pouch, or Multivac Tyvek – Eva-Surlyn-Eva peel pouch, as both are commonly accepted in medical devices as an effective form of sterile barrier packaging. This packaging is the same as the predicate devices and is validated according to the requirements of ISO 11607:2006, *Packaging for Terminally Sterilized Medical Devices* and ASTM D4169-05, *Standard Practice for Performance Testing of Shipping Containers and Systems,* for a shelf life of 5 years.

The application of these standards is outlined individually in the FDA 3654 forms located in Appendix C.

Section 15 Biocompatibility

The materials used in the proposed device include:

Substrate (base electrode material)	300 Series Stainless Steel
Shaft and Tip Insulation (all electrodes)	Polyolefin
Electrode coating	PTFE (Polytetrafluoroethylene)
Printing (angled electrodes will not be printed)	Ink, (Marabu TPU970)
End Cap	Vinyl (Green)
Modified Electrode Distal Tip Insulation (Select versions)	PTFE
Nose Cone	Silicone

As identified in the substantial equivalence discussion (Section 12), the proposed device materials of construction are essentially the same as the predicate devices with the exception of the extended length of PTFE insulation on some configurations of modified electrodes.

Megadyne has completed biocompatibility testing of this device, including the new material, to ensure it is biocompatible in accordance with ANSI/AAMI/ISO 10993-1:2003, *Biological evaluation of medical devices- Part 1: Guidance on selection of tests*, as it applies to tissue/bone/dentin communicating devices with limited contact duration. The specific tests performed are identified below with a summary of the results and the reference test number(s):

Test Performed	Summary of Results	Reference Test Report Number(s)
Cytotoxicity (Agar Overlay)	Minimal Cytotoxic Response	Nelson Laboratories 416881
Irritation (Intracutaneous Reactivity)	Non-irritant	Nelson Laboratories 414644
Sensitization (Magnusson Kligman Method)	Negligible Sensitivity Response	Nelson Laboratories 414643

Section 16 Software

This section does not apply. The proposed device does not contain software.

Section 17 Electromagnetic Compatibility and Electrical Safety

Megadyne has conducted extensive testing of the device to ensure its conformance to the applicable requirements of IEC 60601-1:2005 *Medical Electrical Equipment – Part 1: General Requirements for Safety*, IEC 60601-5-5:2006 *Medical Electrical Equipment – Particular Requirements for the safety of high frequency surgical equipment,* and ANSI / AAMI HF-18:2001, *Electrosurgical Devices*. This product meets or exceeds the requirements of these standards.

The Declaration of Conformance to these standards is provided in Section 9 Declaration of Conformity.

The application of these standards is outlined individually in the FDA 3654 forms located in Appendix C.

Section 18 Performance Testing – Bench

A. Standards Conformance and in vitro Performance Testing

Megadyne has conducted extensive testing of the device to ensure its conformance to the voluntary standard ANSI / AAMI HF-18:2001, *Electrosurgical Devices*. The clauses of the standard which apply to accessories are:

1. Section 4.1.4.1, ***Labeling***

   Conformance with the first requirement of the standard, Labeling, is ensured through Megadyne's standard labeling control and approval procedures.

2. Section 4.2.5.1, *Dielectric withstand, 60 Hz*

   Conformance with the dielectric withstand requirement has been demonstrated using the method specified by the standard. The device performs within the requirements of the standard.

3. Section 4.2.5.4, ***Dielectric withstand of accessories***

   Conformance with the dielectric withstand of accessories requirement has been demonstrated using the method specified by the standard. The device performs within the requirements of the standard.

4. Section 4.3.4, ***Shipping Temperature***

   Conformance with the shipping temperature requirement has been demonstrated using the method specified by the standard. The device performs within the requirements of the standard.

5. Section 4.3.5, *Operating Conditions*
   Conformance with the operating conditions requirement has been demonstrated using the method specified by the standard. The device performs within the requirements of the standard.

The Declaration of Conformance to this and other electrical performance standards is provided in Section 9 Declaration of Conformity.

The application of these standards is outlined individually in the FDA 3654 forms located in Appendix C.

Section 19 Performance Testing – Animal

Following is a study summary of animal testing, with associated appendices, related to the use of the ACE Blade and ACE mode.

Study Summary

(b)(4)

Ryan D. Lewis MD MHA

Chief Medical Officer, Megadyne Medical Products Inc.

May 28, 2008

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

APPENDIX A
STUDY PROTOCOL

(b)(4) Study Protocol (b)(4).

August 7, 2007

Megadyne Medical Products Inc.

11506 South State Street

Draper, Utah 84020

(b)(4) Test Data

(b)(4) Test Data

APPENDIX B
FINAL PATHOLOGY REPORT

(b)(4) Test Data

FINAL PATHOLOGY REPORT

(b)(4) Test Data

STUDY TITLE:
Histopathology of Incision Sites Created by Different Devices: Porcine Study (Non-GLP)

TEST ARTICLE IDENTIFICATION:
Scalpel
Standard Cautery
Prototype Cautery

SPONSOR
Megadyne Medical Products, Inc.
11506 South State Street
Draper, UT 84020

SUBMITTED BY:
(b)(4) Test Data

SUBMITTED TO:
(b)(4) Test Data

REPORT DATE:
11-29-07

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

Section 20 Performance Testing – Clinical

This submission does not rely on nor does it include any data from clinical trials. Reference FDA Form 3674 in Appendix D.

The following is a review of scientific literature related to the use of electrosurgery in skin incisions.

Literature Review: Diathermy use in cutaneous incisions

Ryan D. Lewis MD MHA: Chief Medical Officer, Megadyne Medical Products Inc.

May 22, 2008

While electrosurgery has become an essential surgical technology, historically there has been a reluctance to make cutaneous incisions stemming from concerns about excessive scaring, delayed healing and increased infection when compared to cold scalpel incisions.

Modern electrosurgical generators can produce distinct radio frequency wave forms each having a different surgical effect. Advances in electronics allow the production of a pure sinusoidal "cut" wave form. In contrast to the "coagulate" modes, the cut mode allows tissue cleavage with minimal thermal damage to surrounding tissue. Early studies using what today would be considered outdated electrosurgical technology, revealed concerns about wound healing after skin incision using electrosurgery.[4] These concerns centered around delayed healing, excessive scaring and potential for increased infection. With the advent of modern electronics, wave modulation has evolved to include a pure sinusoidal format able to vaporize tissue with minimal collateral thermal damage. Some bias against using electrosurgery for skin incisions continues to be propagated today.[4]

More recent studies using modern electrosurgical generators able to produce a pure sinusoidal cut wave have demonstrated that concerns about using electrosurgery for skin incisions are unfounded.[1-3, 5-8]

In 1982, Allan and colleagues studied the strength of abdominal incisions in 348 Wistar rats half of the group undergoing incision with scalpel and half electrosurgery.[1] They found no difference between the seventh and tenth postoperative day between individuals undergoing scalpel incisions and those receiving electrosurgical incisions. The seventh to the tenth day was mentioned in this study as the time period when dehiscence is likely to occur.

Vore and colleagues compared skin incisions in a porcine model made with scalpel, standard cut mode electrosurgical incision and a novel electrosurgical electrode tip designed to focus energy with less thermal damage than a standard tip in cut mode.[8] Study endpoints included wound strength at 14 days, thermal tissue damage at time 0 and histological analysis of wound healing characteristics at 14 and 28 days. At 14 days, both electrosurgical devices demonstrated lower burst strength than scalpel incisions but at 28 days those differences were resolved. Histological analysis at 14 and 28 days showed similar healing between the novel electrosurgical electrode and scalpel with standard electrosurgery causing more fibroplasias indicating a slight delay in wound organization. Wound strength tests and time delayed histological analysis results were supported by the T0 analysis of incisional margin damage. What is described in the paper as the "zone of coagulation necrosis" was measured in millimeters from the incision edge to normal tissue. A 2:1:0 ratio was noted between standard electrosurgical cut mode, the novel electrosurgical electrode and scalpel respectively. This study demonstrates advances in

electrosurgical technology which more closely approximates cutaneous incisions made with a cold scalpel.

Several human studies have been done which demonstrate the utility of electrosurgery for cutaneous incisions. Dixon and Watkins studied 84 consecutive patients undergoing either inguinal heriorrhaphy or open cholecystectomy randomized to incisions made with a scalpel or incisions made with an electrosurgical needle used in cut mode after scoring the incision with a scalpel.[3] Endpoints for this study included ease of use, post operative pain and cosmetic appearance of the healed cutaneous wound. Dixon and Watkins found incision with electrosurgery to be significantly faster than scalpel. There were few wound complications over all. There was no significant difference in postoperative pain scores between the two groups. Interestingly subjective cosmetic assessment of the healed incisions showed a preference for the electrosurgery incisions at 6 weeks over those made by the scalpel. It is however unclear if the evaluators were blinded to the assigned group.

Kearns and colleagues randomized 100 consecutive patients undergoing elective midline laparotomy to either electrosurgical incision or scalpel.[6] All layers were incised with either scalpel or electrosurgery. Electrosurgery was used for hemostasis in both groups. Wound related pain scores and the number of days patient controlled analgesia (PCA) required were recorded by blinded observers. Wound complications were recorded by an observer blinded to the method of incision. Kearns and colleagues found a significant reduction in pain scores in the electrosurgery group at postoperative days 1 and 2 as

compared to patients in the scalpel incision group. No significant difference was noted on the 3rd day and subsequent days. PCA requirement was significantly less in the electrosurgery group. Total wound complications were few and there was no significant difference between groups. These investigators felt that there was a significant advantage to using electrosurgery for midline incisions when comparing the endpoints of wound healing and postoperative discomfort.

B. Sheikh studied patients undergoing neurosurgical procedures.[7] Each of the 177 skin incisions included in the study were divided in half and half of the incision was made with cold scalpel and the other half with micro-needle electrosurgery. Wound edges were immediately inspected for differences in appearance between the segment made with scalpel and that made by electrosurgery. Other parameters noted were the time of incision and wound inspection on postoperative days 1, 3 and 14. Electrosurgical incisions were found to take less time than scalpel incisions on average. When inspecting the wound edges for viability, color, presence of char, and dermal peeling, there was no macroscopic difference between scalpel and electosurgery. Also, no differences in healing were noted between the two halves of the incision during the postoperative inspection at days 1, 3 and 14. Dr. Sheikh concluded that electrosurgery is both "safe and useful" for cutaneous incision in neurosurgical procedures.

In a group of 125 consecutive patients scheduled for tension-free inguinal hernioplasty, Chrysos and colleagues compared incisions made with either electrosurgery or cold scalpel.[2] Measured parameters included blood loss during skin incision, postoperative

pain requiring analgesics, presence of wound dehiscence, and postoperative wound infection on day of discharge, the day of staple removal and at 1 month follow up. The investigators found no difference in blood loss between the groups. Postoperative analgesia use was approximately twice as much in the scalpel incision group as compared to patients undergoing electrosurgical incisions during the first 2 days. No difference was noted between the groups wound healing characteristics at the time of discharge, removal of the staples and at 1 month follow up. Chrysos and colleagues indicated that this study "clearly supported the use of electocautery in performing skin incisions".

In summary, the studies described above support the equivalence and potential advantages of using electrosurgery for skin incisions when compared to cold scalpel. No differences in wound healing or wound strength were noted between these two modalities. Potential benefits of electrosurgery over scalpel include postoperative pain reduction and time required to make the incision. New technologies related to electrosurgery have decreased or eliminated the tissue effect gap between electrosurgical incisions and scalpel incisions.

References

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2. Chrysos E, Athanasakis E, Antonakakis S, Xynos E, Zoras O. A prospective study comparing diathermy and scalpel incisions in tension-free inguinal hernioplasty. Am Surg. 2005 Apr;71(4):326-9.

3. Dixon AR, Watkin DF. Electrosurgical skin incision versus conventional scalpel: A prospective trial. J R Coll Surg Edinb. 1990 Oct;35(5):299-301.

4. Glover JL, Bendick PJ, Link WJ. The use of thermal knives in surgery: Electrosurgery, lasers, plasma scalpel. Curr Probl Surg. 1978 Jan;15(1):1-78.

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8. Vore SJ, Wooden WA, Bradfield JF, Aycock ED, Vore PL, Lalikos JF, et al. Comparative healing of surgical incisions created by a standard "bovie," the utah medical epitome electrode, and a bard-parker cold scalpel blade in a porcine model: A pilot study. AnnPlast Surg. 2002 Dec;49(6):635-45.

(b)(4) Schematic Drawing

(b)(4) Schematic Drawing

(b)(4) Schematic Drawing

(b)(4) Schematic Drawing

Appendix B Predicate Device IFU and Brochures

MEGADYNE®

11506 SOUTH STATE STREET
DRAPER, UTAH 84020 USA
Phone +1 (801) 576-9669 +1 (800) 747-5510 (USA)
Fax +1 (801) 576-9698 +1 (888) 747-3774 (USA)

CAUTERY TIP

INSTRUCTIONS FOR USE

Cautery Tips (or "electrodes") are designed to fit most electrosurgical pencils and other electrosurgical accessories. Prior to use, ensure the electrode has the proper compatibility and fit with the accessory.

To place the electrode into an electrosurgical accessory:

1. Ensure the accessory is not connected to the generator.
2. Fully insert the electrode into the accessory. Make sure the insulation sleeve fits securely inside the accessory.
3. If the insulating sleeve does not fit securely inside the accessory, do not use the electrode.
4. Some electrodes are supplied with a tip protector. If the tip protector is present, remove prior to use.

WARNING

- **When not in use, store electrode in an electrically insulated container.**
- **Cautery tips that are activated or hot from use can cause a fire. Do not place them near or in contact with flammable material and substances (e.g. drapes, flammable gases, endotracheal tubes, etc.)**
- **Electrosurgery should not be used to perform circumcisions.**
- **Use the lowest possible power setting to achieve the desired effect.**

CAUTION

- **These devices are intended for single use only. Properly discard after use. Do not resterilize.**
- **If the electrode is damaged, discard the electrode.**
- **Refer to the generator manufacturer's operation manual for proper usage of electrosurgical generator(s).**
- **Federal (USA) law restricts this device to sale by or on the order of a physician.**
- **Activate electrodes when in contact, or in close proximity to target tissue to avoid the possibility of unintended tissue damage.**

EU Authorised Representative
Quality First International Limited
20 Eversley Road, Bexhill-on-Sea
East Sussex, TN40 1HE
United Kingdom

STERILE R

Do Not Use If Package Is Damaged

Latex Free

CE
0030

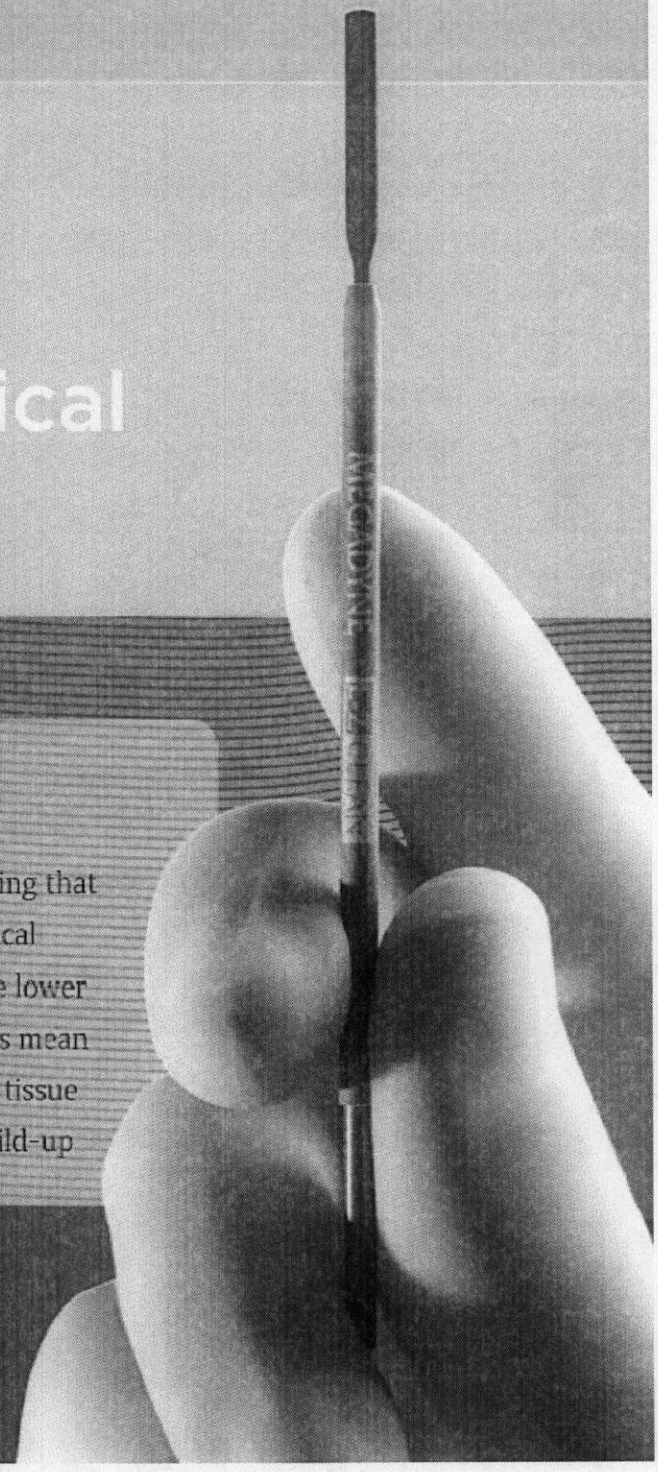
MEGADYNE®

3000061 01 REV E 2003.04.11

MEGADYNE

E-ZCLEAN®

E-Z Clean Non-Stick Electrosurgical Tips



E-Z Clean™ non-stick electrodes feature a patented and proprietary polytetrafluoroethylene (PTFE) coating that reduces eschar build-up during surgical procedures, enabling surgeons to use lower power settings. Lower power settings mean less thermal necrosis to surrounding tissue and a further reduction in eschar build-up

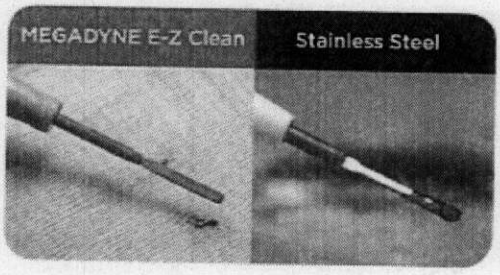
Cost-Effective Non-Stick Electrosurgery Tips For a Variety of Surgical Procedures

MEGADYNE

E-Z CLEAN NON-STICK ELECTROSURGICAL TIPS

E-Z CLEAN NON-STICK ELECTROSURGICAL TIPS

Trusted by Thousands of Surgeons Worldwide



- With more than two-dozen tip configurations and sizes, Megadyne offers blade, needle, and ball electrodes to meet the needs of numerous electrosurgery procedures.
- The green E-Z Clean modified tips are insulated everywhere but the distal 3-5 mm of the electrode shaft, minimizing the likelihood of damage to surrounding tissue.
- Surgeons can get the performance of Megadyne's E-Z Clean nonstick tips for every procedure at costs comparable to stainless steel with our pencil and tip savings program. Contact us at 800-747-6110 for a free sample of an E-Z Clean Tip and to learn about this program.

IF IT ISN'T GREEN, IT ISN'T MEGADYNE E-Z CLEAN®

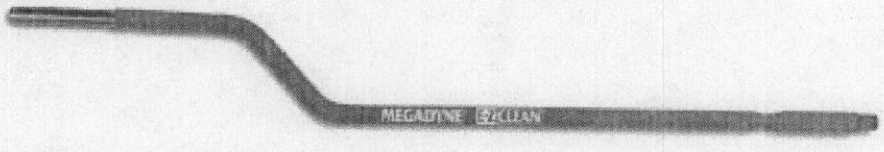
MEGADYNE E-Z CLEAN

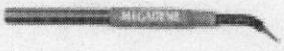
Description	Catalog Number	Qty Per Case
Coated Blade Electrodes		
 2.5 inch (6.35 cm), Standard Blade Electrode	0012	12
 2.5 inch (6.35 cm), Standard Blade Electrode Modified	0012M	12
 2.75 inch (7 cm), X-Long Standard Blade Electrode	0012A	12
 2.75 inch (7 cm), X-Long Standard Blade Electrode Modified	0012AM	12
 4 inch (10.2 cm), Extended Blade Electrode	0014A	12
 4 inch (10.2 cm), Extended Blade Electrode Modified	0014AM	12
 6.5 inch (16.5 cm), Extended Blade Electrode	0014	12
 6.5 inch (16.5 cm), Extended Blade Electrode Modified	0014M	12

E-Z CLEAN NON-STICK ELECTROSURGICAL TIPS

Description	Catalog Number	Qty Per Case
Coated Needle Electrodes		
 2.75 inch (7 cm), Needle Electrode	0013	12
 2.75 inch (7 cm), Needle Electrode Modified	0013M	12
 4 inch (10.2 cm), Extended Needle Electrode	0016A	12
 4 inch (10.2 cm), Needle Electrode Modified	0016AM	12
 6 inch (15.2 cm), Extended Needle Electrode	0016	12
 6 inch (15.2 cm), Extended Needle Electrode Modified	0016M	12
Blunt Needle Electrodes		
 2.75 inch (7 cm), Blunt Needle Electrode	0113	12
 2.75 inch (7 cm), Blunt Needle Electrode Modified	0113M	12
 4 inch (10.2 cm), Blunt Needle Electrode	0113A	12

MEGADYNE E-Z CLEAN

Description	Catalog Number	Qty Per Case
Coated Ball Electrodes		
 2 inch (5.1 cm), Ball Electrode	0015	12
 5 inch (12.7 cm), Ball Electrode	0009	12
Coated Specialty Electrodes		
 Bayonet Needle Electrode	0028	12
 Bayonet Needle Electrode Modified	0028M	12
 Bayonet Blade Electrode Modified	0029M	12

Description	Catalog Number	Qty Per Case
MEGAfine Needle Electrodes		
 2 inch (5.1 cm), MEGAfine Needle Electrode	0118	12
 2.5 inch (6.35 cm), Extended MEGAfine Needle Electrode	0118A	12
 2 inch (5.1 cm), Angled MEGAfine 45 Degree	0119	12
 2 inch (5.1 cm), Angled MEGAfine 45 Degree 3mm	0119A	12
 2.5 inch (6.35 cm), Angled MEGAfine 90 Degree	0120	12
 6.5 inch (16.5 cm) MEGAfine Needle	0121	12

Accessories. Any reusable accessories should be periodically tested for function and safety in accordance with their manufacturer's instructions. Use only accessories whose connectors match those on the generator. Adapters should not be used unless they are approved by the ESU manufacturer.

Power Deficiencies. The output setting selected should be as low as possible for the intended purpose. An apparent power deficiency may indicate faulty application of the dispersive electrode or failure of a patient lead. The patient circuit, including the active cable, pencil, and dispersive electrode, should always be checked before increasing the output setting.

Interference. ESUs may interfere with other electronic devices, particularly cardiac pacemakers. Precautions should be taken to ensure the patient's well being in the event of such interference. These precautions should include:

- Secure attachment of the dispersive electrode.
- Placement of the dispersive electrode away from the heart and as close as possible to the surgical site.
- Other precautions as directed by the pacemaker provider.

Sparks. The sparks generated in ES cutting or coagulation can easily ignite flammable substances at the surgical site. The use of flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen should be avoided if a surgical procedure is carried out in the region of the thorax or the head. Unless these agents are drawn away or category AP equipment is used. Non-flammable agents should be used for cleaning and disinfection wherever possible. Flammable agents used for cleaning or disinfection or as solvents of adhesives should be allowed to evaporate before the application of the ES device. There is a risk of pooling of flammable solution under the patient or in body depressions such as the umbilicus and body cavities such as the vagina. Any fluid pooled in these areas should be removed before the ES equipment is used. Attention should be called to the danger of ignition of endogenous gases. Some materials, for example, cotton, wool, and gauze, may be ignited by sparks produced in normal use of the ES generator.

Additional Information

Additional information can be obtained from Utah Medical Products or its authorized distributors.

UTAH MEDICAL PRODUCTS INC

EC REP

United States

Utah Medical Products, Inc.
7043 South 300 West
Midvale, Utah 84047
(800) 533-4984
(801) 566-1200

Utah Medical Products Ltd.
Athlone Business and Technology Park
Dublin Road
Athlone, County Westmeath
Ireland

pn 59191 rev 071105

UTAH MEDICAL PRODUCTS INC

EPITOME SCALPEL

Epitome® .2 Scalpel Electrode with ZapGuard™ Instructions for Use

Product Description

The Epitome Scalpel is a sterile, single use disposable blade electrode for use with most electrosurgical units (ESUs). Epitome utilizes a rugged tungsten wire that is supported by a non-conductive ceramic core. The fine gauge tungsten wire provides a high concentration of electrosurgical (ES) current at the edge of the blade. The ceramic eliminates distribution of current from the sides of the blade, and provides mechanical strength. The result is an electrosurgical blade that:

- *provides an effortless and smooth cut for precise incisional control*
- *cuts quickly and efficiently without counteraction*
- *significantly reduces thermal injury to the surgical site and adjacent sites*
- *provides for precise control of hemostasis during cutting*
- *substantially reduces the buildup of tissue on the blade*
- *decreases or eliminates the need to repeatedly clean off the blade*

The silicone ZapGuard is designed to protect the user and patient from shock and burn from unintentional contact with the joint between the Epitome and the ES pen. The ZapGuard minimizes shock risk in two ways. 1) by establishing a dual seal and thus minimizing electrical conduction between the patient and electrode/pen joint, and 2) by increasing the separation distance between the electrode/pen joint and tissue.

Specifications

Catalog Number	Description
CBE-220	Epitome 2 Scalpel with ZapGuard, standard shaft
CBE-270	Epitome 2 Scalpel with ZapGuard, extended shaft

Material

Wire material	0.2mm (.008") diameter tungsten
Blade material	Ytria Partially-Stabilized Zirconia Ceramic (Radiopaque)
Shaft:	Stainless steel
Shaft Insulation	Polyolefin
ZapGuard:	Silicone

Maximum Power: Cutting/Contact Coag: 150 Watts
Spray Coag/Fulguration: 120 Watts, 2 sec. maximum bursts, with minimum 2 sec. between bursts; 60 Watts Continuous

Dimensions

	CBE-220	CBE-270
Catalog Number		
Blade Length	16" (4.1mm)	16" (4.1mm)
Blade Width	.11" (2.8mm)	.11" (2.8mm)
Blade Thickness	.023" (.58mm)	.023" (.58mm)
Shaft Diameter	3/32" (2.4mm)	3/32" (2.4mm)
Overall Length	2.36" (60mm)	6.30" (161mm)
Maximum Bend	90°	
Bend Range from tip	.50" - .80" (13mm - 20mm)	

2 **Single Use Only**

STERILE EO **Sterilized by Ethylene Oxide**

LATEX FREE *Epitome electrodes are latex-free*

CE 0050

Warning

Content is sterile. Do not use if package is damaged or opened.

Important Operational Precautions

Be Familiar With Power Settings, Modes, and Guidelines. Because the ES power is concentrated at the wire, Epitome requires a lower ESU power setting as compared to conventional blade electrodes. In addition, Epitome will produce less thermal damage to the tissue along the margins of the cut, and consequently will produce less hemostasis. As a result, it is strongly suggested that users familiarize themselves with the performance of Epitome by practicing their technique on an appropriate tissue simulator (e.g., beef tongue or heart). The objective of this exercise is to determine the cutting characteristics of the blade through the tissue at various power settings.

As an initial point of reference, soft tissue dissection with Epitome can be accomplished with settings as low as 10-20 watts. Fibrotic and adipose tissues will typically require higher settings. Ideal power settings are noted by dissection with minimal mechanical resistance. For highly adipose tissue dissection, the Epitome 4 (blue) electrode is recommended.

UTMD does not recommend use of the CoAG mode for tissue dissection. Epitome will dissect most efficiently when the CUT mode (Cut) or "Blend" waveform is used.

Avoid Excessive Side Forces to Ceramic. Applying excessive lateral (side or edge) force to the Epitome ceramic may cause separation of the wire from the ceramic and/or ceramic breakage.

Use Proper Intra-Operative Cleaning Techniques. Because Epitome's ceramic core resists heat, electrode tip may be significantly recused compared to standard ES blades. As a result, cleaning of Epitome during procedures should be done with a wet gauze within the sterile field.

- Do not use abrasives, such as the scratch pads commonly used with some ES devices.
- During cleaning, avoid edge forces on the ceramic and wire – clean Epitome by gently pulling the side (NOT the wire edge) of the Epitome blade across a wet gauze in a longitudinal direction (i.e., from base to tip).
- Do not pull or rock the ceramic. Using excessive force. Avoid pinching or stretching the delicate wire.

Always verify that the electrode remains fully seated in the ES pen after each cleaning.

Indications

The Epitome blade electrodes are intended for use in virtually every surgical discipline where flat, needle-type ES blades are used for making straight cuts through tissue. The Epitome 2 series of electrodes are intended for use in procedures that require cuts where only light or no hemostasis is desired. The greater level of hemostasis, as desired, Utah Medical Products offers the Epitome 4 series (blue) blade electrodes.

Instructions for Use

1. Select an Epitome electrode, keeping the peel pouch unopened, and sterile.
2. Perform the necessary preparations that lead to the ES portion of the procedure.
3. When ready to use the Epitome, remove it from its peel pouch utilizing aseptic technique.
4. If desired, bend the Epitome electrode up to 90 degrees on the flat portion of the shaft only. Do not attempt to bend near the ceramic portion of the Epitome blade.
5. Insert Epitome into the ES pen, ensuring that the uninsulated portion of the shaft is fully inserted into the pen and the Zag-Guard provides a good seal against the nose of the ES pen. Also, take care to insert the blade in the desired alignment. ***Do not insert or twist the device using the blade portion; always handle the device by the insulated shaft.***
6. Adjust the generator output setting and mode as appropriate for the procedure to be performed (see Important Operational Precautions).
7. Activate the ESU and perform the ES portion of the procedure.
8. To remove the Epitome electrode, grasp the insulated shaft and simply pull the electrode from the ES pen.
9. Dispose of the used electrode with other medical waste.

Compatibility

The Epitome electrode may be used with any ESU and ES pen that accepts flat (2.36mm) diameter electrodes. Consult the ESU manufacturer for additional information regarding recommendations for output power settings.

Storage

The Epitome electrodes should be kept in their original box to avoid the possibility of pouch damage and subsequent compromise of sterility of the electrodes. Do not place heavy items on top of these boxes as this may also lead to pouch damage.

Store the electrodes at room temperature. Minimize exposure to high humidity and condensation.

Electrosurgery Precautions and Warnings

Many ESUs have been designed with various features to ensure patient and operator safety. The remaining burden for patient and operator safety lies with the user of the device. The most important safety factors that are under control of the operator are delineated below. It is important that these points be read and understood before performing ES procedures.

Inspection. When the ESU is unpacked after transport between locations, as well as periodically with ordinary use, visually inspect the unit and all accessories for damage or missing parts. Do not use the unit without correcting any observed or suspected damage.

Dispersive electrode pad. A high-quality and properly placed dispersive electrode is the key element in achieving safe, effective electrosurgery. Direction for the proper use of the dispersive electrodes are provided with the dispersive electrodes. These directions should be rigorously followed to prepare, apply maintain, and remove the dispersive electrode.

If the patient moves after application of the dispersive electrode, the contact between the electrode and the patient should be rechecked before proceeding with the surgical procedure.

Skin-to-skin contact (e.g., between the arms and body of the patient) should be avoided, for example, by the insertion of dry gauze. This practice aids in preventing the establishment of alternate current paths.

Grounding. All the frequencies and power levels used in electrosurgery, any grounded metal parts may conduct current away from the patient with sufficient concentration at the contact point to cause a burn. Although the isolated lead system of many ESUs is usually effective in limiting this leakage current and preventing such burns, there are circumstances where this precaution may be accidentally subverted and stray currents may flow. In addition, some ESUs do not incorporate isolated leads and require special attention to ensure patient and operator safety from the hazards of stray ES currents. Therefore, the patient should not have incidental contact with metal parts which are grounded or which have an appreciable capacitance to ground.

Leads. Unshielded active and return leads should be positioned so that they cannot come into contact with the patient or with other leads connected to the patient. They should also not be allowed to run closely parallel to other leads.

Monitoring Leads. Electrodes and probes connected to monitoring, stimulating, or imaging devices (e.g. ECG electrodes) can provide paths for stray ES currents which may cause burns. This is possible even though these electrodes and probes are battery operated, insulated, or isolated at 50/60Hz. The risk can be minimized by placing the electrodes or probes as far away from the surgical site and dispersive electrode as possible. Protective impedances in the monitoring leads can help reduce the risk of burns. Electrodes covering wide areas are best, and needle-type monitoring electrodes should *never* be used during electrosurgery.

Active Electrode. The surgeon handling the active electrode must, of course, avoid applying the active electrode to any part of his/her own body. The surgeon must also be aware that if the active electrode is touched to any conductive tool or appliance that device becomes an extension of the active electrode and can cause burns to either the patient or the surgeon. When not being used, the active electrode should be stored isolated from the patient.

Cold Scalpel Healing with Electrosurgical Modality

- Precise Dissection Yields Excellent Cosmetic Results
- Low Power Settings Reduce Smoke Plume
- Provide Hemostasis
- Favorable Healing Process

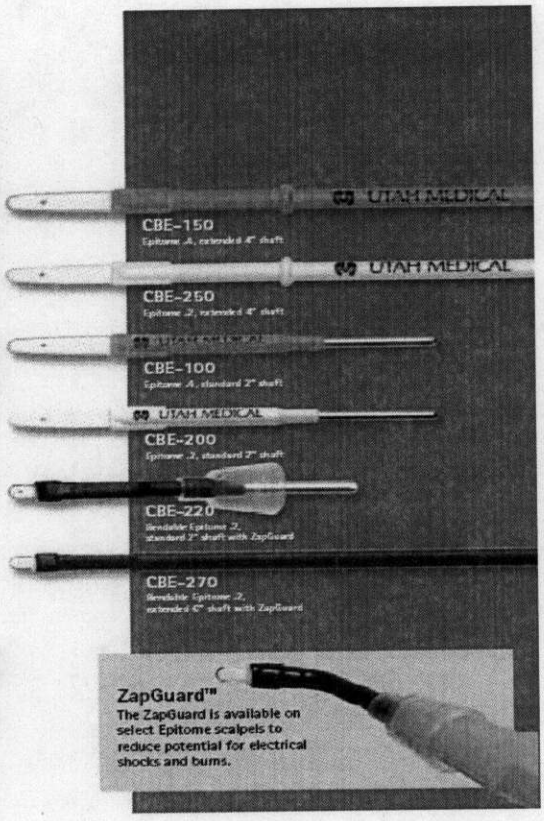
Epitome® Scalpel

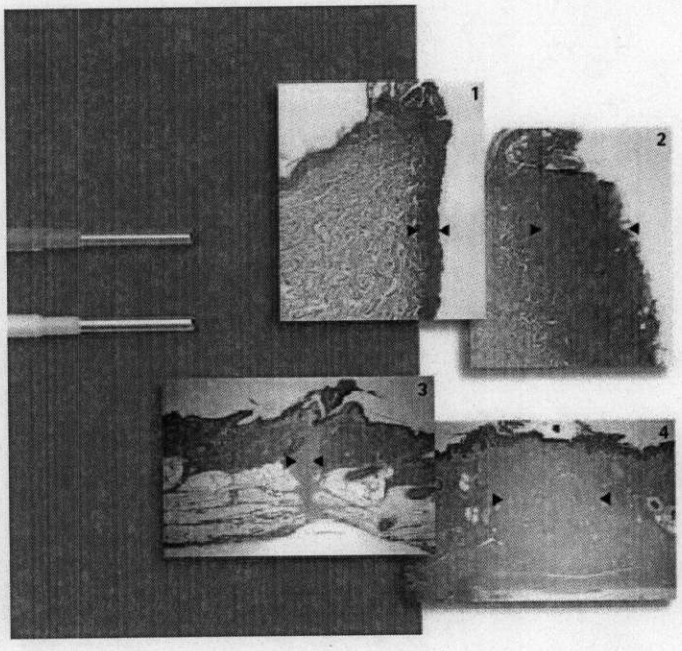
Epitome, UTMD's patented[1] blade electrode, significantly reduces thermal tissue injury compared to standard blade tips. In fact, histological analysis of porcine skin incisions shows healing results that closely resemble cold sharp scalpel incisions[2]. This means that Epitome provides:

- Cutting precision exceeding that of a cold scalpel
- Cosmetic results comparable to a cold scalpel
- Hemostasis of the electrosurgical modality
- Improved Wound Healing

External Lesion Electrodes

UTMD's short shaft electrodes are ideal for controlled removal of external lesions, allowing better utilization of office-based ESUs. Excision of lesions provides a specimen for dermatopathology, which is not possible with ablative modalities such as cryotherapy.





Reduce Thermal Injury
Histology reveals significantly reduced thermal injury with Epitome incisions (1) as compared to a standard electrosurgical tip incision (2).

Improved Wound Healing
Mason's Trichrome stain reveals markedly reduced fibroplasia, as shown by the degree of collagen deposition, and minimized inflammatory response in porcine skin incisions made with Epitome (3) as compard to a standard tip incision (4).

Appendix C FDA Form 3654

Copies of FDA Form 3654 follow this page

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

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]

ANSI/AAMI HF18 – Electrosurgical Devices – 2001

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 006	
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?	☒	☐
ɔes 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 the standard? 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], www.fda.gov/cdrh/stdsprog.html

[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 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 of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

PSC Graphics: (301) 443-1090 EF

137

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
NSI/AAMI HF18 – ELECTROSURGICAL DEVICES – 2001

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1-3	Scope, Normative References, and Terms and Definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
4.1 Labeling; 4.2.5.1 Dielectric Withstand 60 Hz; 4.2.5.4 Dielectric Withstand of Accesories; 4.3.4 Shipping Temperatures; 4.3.5 Operating Conditions

DESCRIPTION
Used methods for active electrodes

JUSTIFICATION
Device is an active electrode and is NOT a generator and therefore is only required to meet the standard as it applies to active electrodes.

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

TYPE OF DEVIATION OR OPTION SELECTED*
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

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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]

IEC 60601-1-2005 - Medical Electrical Equipment - 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]	# 5-4	
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 the standard? 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], www.fda.gov/cdrh/stdsprog.html

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

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-1-2005 - MEDICAL ELECTRICAL EQUIPMENT - GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1-3	Scope object and related standards, Normative references, Terminology and definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	General Requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
4.1 Conditions for application to ME Equipment or ME Systems; 4.2 Risk Management Process for ME Equipment or ME systems; 4.4 Expected Service life; 4.5 Equivelent safety for ME Equipment or ME Systems; 4.6 ME Equipmetn or ME System parts that contact the patient

DESCRIPTION
Apply methods that apply to active electrodes

JUSTIFICATION
Device is an active electrode accessory and is NOT a generator and therefore is only required to meet the standard as it applies to active electrode accessories.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
	General requirements for testing ME Equipment	☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
5.1 Type Tests; 5.2 Number of samples; 5.3 Ambient temperature, humidity, atmospheric pressure; 5.4 Other conditions

DESCRIPTION
Apply methods that apply to active electrodes

JUSTIFICATION
Device is an active electrode accessory and is NOT a generator and therefore is only required to meet the standard as it applies to active electrode accessories

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

IEC 60601-1-2005 - MEDICAL ELECTRICAL EQUIPMENT - GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Classification of ME Equipment and ME Systems	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
6.4 Method(s) of sterilization

DESCRIPTION
Apply methods that apply to active electrodes

JUSTIFICATION
Device is an active electrode accessory and is NOT a generator and therefore is only required to meet the standard as it applies to active electrode accessories.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	ME Equipment identification, marking and documents	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
7.2.1 Minimum requirements for marking on ME Equipment and on interchangable parts; 7.2.3 Consuylt accompanying documents; 7.2.4 Accessories; 7.6.1 Explanation of symbols; 7.9.1 General; 7.9.2 Instructions for use;

DESCRIPTION
Apply methods that apply to active electrodes

JUSTIFICATION
Device is an active electrode accessory and is NOT a generator and therefore is only required to meet the standard as it applies to active electrode accessories.

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

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-2-2-2006 - Medical Electrical Equipment - Particular requirements for the safety of high frequency surgical equipment

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 6-197	
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 the standard? 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: _____

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[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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142

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

C 60601-2-2-2006 - MEDICAL ELECTRICAL EQUIPMENT - PARTICULAR REQUIREMENTS FOR THE SAFETY OF HIGH FREQUENCY SURGICAL EQUIPMENT

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1-3	Scope, Terminology and definithions, General requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
59.103	Active Accessory Insulation	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
59.103.6 HF Dielectric Strength; 59.103.7 Mains Dielectric Strength

DESCRIPTION
Used methods for active electrodes

JUSTIFICATION
Device is an active electrode and is NOT a generator and therefore is only required to meet the standard as it applies to active electrodes.

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

TYPE OF DEVIATION OR OPTION SELECTED*
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 11135-1:2007 Sterilization of health care products - Ethylene Oxide - Requirements for development, validation and routine control of a sterilization process for medical devices.

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 14-228	
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 the standard? 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: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

O 11135-1:2007 STERILIZATION OF HEALTH CARE PRODUCTS - ETHYLENE OXIDE - REQUIREMENTS FOR DEVELOPMENT, ALIDATION AND ROUTINE CONTROL OF A STERILIZATION PROCESS FOR MEDICAL DEVICES.

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1-3	Scope, Normative references, Terms and definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4 - 8	Quality Management Systems, Sterilizing agent characterization, Process and equipment characterization, Product Definition, Process Definition	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ECTION NUMBER - 12	Validation, Routine monitoring and control, Product release from sterilization, Maintaining process effectiveness.	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-1: 2003 Biological evaluation of medical devices - Part 1: Evaluation and testing

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 2-98	
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?	☒	☐
oes 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 the standard? 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: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
) 10993-1: 2003 BIOLOGICAL EVALUATION OF MEDICAL DEVICES - PART 1: EVALUATION AND TESTING.

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1-3	Scope, Terms and definitions, General principals applying to biological evaluation of medical devices	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Categorization of medical devices, Testing, Selection of biological tests, Assurance of test methods	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
4.2.3 (b) and 4.3 (a) selected

DESCRIPTION
Device is an external communicating devices applied to tissue/bone/dentin for limited contact duration

JUSTIFICATION
Appropriate for device intended use even in multiple use situations

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
CTION NUMBER /	Testing, Selection of biological tests, Assurance of test methods	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-7:1995, Biological Evaluation of Medical Devices – Part 7 Ethylene Oxide Sterilization Residuals

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 14-76	
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.	☒	☐
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If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
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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: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

) 10993-7:1995, BIOLOGICAL EVALUATION OF MEDICAL DEVICES – PART 7 ETHYLENE OXIDE STERILIZATION RESIDUALS

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1-3	Scope, Normative References, and Definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4-5	Requirements and Product Release	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
As they apply to limited exposure devices

DESCRIPTION
Electrosurgical electrodes are used for limited duration

JUSTIFICATION
Contact duration, even in multiple use situations, is generally less than 24 hours

CTION 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.

Paperwork Reduction Act Statement

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Rockville, MD 20850

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

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]

ISO 11607-1 Packaging for terminally sterilized devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 14-193	
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?	☒	☐
oes 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 the standard? 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], www.fda.gov/cdrh/stdsprog.html

[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 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 of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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150

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
) 11607-1 PACKAGING FOR TERMINALLY STERILIZED DEVICES - PART 1: REQUIREMENTS FOR MATERIALS, STERILE BARRIER _ STEMS AND PACKAGING SYSTEMS

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1-4	Scope, Normative references, Terms and definitions, General Requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Materials and preformed sterile barrier systems	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

'CTION NUMBER	SECTION TITLE	CONFORMANCE?
,	Design and development requirements for packaging, Information to be provided	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* 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

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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:

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1350 Piccard Drive
Rockville, MD 20850

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

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 11607-2 2006 PACKAGING FOR TERMINALLY STERILIZED DEVICES - PART 2: VALIDATION REQUIREMENTS FOR FORMING, SEALING AND ASSEMBLY PROCESSE

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 14-194	
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 the standard? 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], www.fda.gov/cdrh/stdsprog.html

[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 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 of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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152

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
11607-2 2006 PACKAGING FOR TERMINALLY STERILIZED DEVICES - PART 2: VALIDATION REQUIREMENTS FOR FORMING, SEALING AND ASSEMBLY PROCESSES

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1-4	Scope, Normative references, Terms and definitions, General Requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Validation of packaging processes	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

CTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Packaging system assembly	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* 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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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

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]

ASTM D4169-05 Standard Practice for Performance Testing of Shipping Containers and Systems

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 14-199	
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 the standard? 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], www.fda.gov/cdrh/stdsprog.html

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

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[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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154

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
1169-05 STANDARD PRACTICE FOR PERFORMANCE TESTING OF SHIPPING CONTAINERS AND SYSTEMS

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1-5	Scope, Referenced Documents, Terminology, Significance and Use, Test Speciman	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6-9	Conditioning, Acceptance Criteria, Procedure, Hazard Elements and Test Schedules	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ECTION NUMBER) - 12	Schedule A - Handling-Manual and Mechanical, Schedule B - Warehouse Stacking, Schedule D - Stacked Vibration and Schedule E - Vehicle Vibration	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
10.2 Manual Handling, 11.2 test levels, 12.3 Schedule E - Vehicle Vibraiton

DESCRIPTION
Table 1 Distribution Cycle 3 - Single package environment, up to 100 lb.

JUSTIFICATION
Product is shipped in cases using common motor freight carrier

* 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.

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Appendix D FDA Form 3674

A copy of FDA Form 3674 follows this page

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
Megadyne Medical Products, Inc.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
24 June 2008

3. ADDRESS *(Number, Street, State, and ZIP Code)*
11506 South State Street

4. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) 801 576 9669 ext. 805
(Fax) 801 576 9698

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)

E-Z Clean Electrosurgical Electrodes

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)
Ronda K Magneson

12. NAME AND TITLE OF THE PERON WHO SIGNED IN NO. 11
(Name) Ronda K. Magneson
(Title) Director of Regulatory Affairs

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12)*
11506 South State Street
Draper, UT 84020

14. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) 801 576 9669 ext. 805
(Fax) 801 576 9698

15. DATE OF CERTIFICATION
24 June 2008

FDA-3674 (1/08) (FRONT)

PSC Graphics: (301) 443-1090 EF

157

Instructions for Completion of Form FDA 3674

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))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/ submission which the certification accompanies. The name must be identical to that listed on the application/submission.

2. **Date** - This is the date of the application/submission which the certification accompanies.

3. **& 4.** - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.

5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/ cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.

6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."

7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/ submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.

8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field.

9. **Certification** - This section contains three different check-off boxes.
   Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/ submission which the certification accompanies.

   Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply to any of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.

   Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply at the time of submission to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/ submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.

10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as NCT will be added automatically before number. Include any and all NCT numbers assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.

12. **Name and Title of Person Who Signed in number 11.** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.

13. **& 14.** - Provide the full address, telephone and fax number of the person who is identified in number 11 and signs the certification in number 11.

15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the applicable address below.

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
Form No. FDA 3674
5901-B Ammendale Road
Beltsville, MD 20705-1266

Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville, MD 20852-1448

Food and Drug Administration
Center for Devices and Radiological Health
Program Operations Staff (HFZ-403)
9200 Corporate Blvd.
Rockville, MD 20850

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FDA-3674 (1/08) (BACK)

158

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

COVER SHEET MEMORANDUM

From: Reviewer Name Atiq Chowdhury

Subject: 510(k) Number K081791/S1

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, Withdrawn, etc.).

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?			✓
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)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
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)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, 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			✓

Rev. 7/2/07

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	Contact OSB.		
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
21 CFR §78.4400	II	GEI

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

Additional Product Codes:

Review: _____ (Branch Chief) GS03 (Branch Code) 10/21/08 (Date)

Final Review: _____ for mm (Division Director) 10/21/08 (Date)

Premarket Notification [510(k)] Review
Traditional

K081791/S1

DATE: October 15, 2008
TO: The Record
FROM: Atiq Chowdhury (Biomedical Engineer)

OFFICE: ODE
DIVISION: DGRND

510(K) HOLDER: Megadyne Medical Products
DEVICE NAME: E-Z Clean Electrosurgical Electrode
CONTACT: Ronda K. Magneson, Director of Regulatory Affairs
11506 South State St.
Draper, UT 84020
PHONE: (801)-576-9669
FAX: (801)-576-9698
EMAIL: magneson@megadyne.com

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce the E-Z Clean Electrosurgical Electrode. Under this submission the sponsor is seeking clearance to market this new device for Prescription Use and as a Class II device. I recommend that the subject device, E-Z Clean Electrosurgical Electrode), is found SE to its predicates in regard to indications of use, design, technical specifications, biocompatibility, materials, sterility, labeling, safety and effectiveness. There are no significant differences which raise issues of safety.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)		X	
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

III. 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	

	Yes	No	N/A
Does the device design use software?		X	
Is the device sterile?	X		
Is the device reusable (not reprocessed single use)?		X	
Are "cleaning" instructions included for the end user?			

The device is a monopolar electrosurgical electrode that is coated with polytetraflouroethylene (PTFE). The sponsor states it is intended for general electrosurgical use, and is designed to fit into and work in conjunction with an industry standard hand- or foot-designed activated electrosurgical pencil which is connected to an electrosurgical generator.

The device is available in a number of tip configurations and lengths. Tips such as standard blades, modified blades, needles, blunt needles, and ball-ends. The device also contains the option of a guard or nonsecone on some configurations of blades (5). This nose cone provides additional dielectric protection at the junction where the electrode is connected to the electrosurgical pencil. The sponsor states the device also includes some tip configurations with a specific geometry to enhance the effects of the ACE (Advanced Cutting Effect, cleared ESU K050579) without causing the blanching and thermal damage typically seen with the use of standard electrosurgical electrodes when making skin incisions (See Animal Testing).

IV. Indications for Use

The indication for use as given in the IFU statement (Section 4) is, "E-Z Clean electrosurgical electrodes are intended to conduct radio frequency (RF) current for cutting and coagulation from the RF electrosurgical generator to target soft tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization. Some tip configurations have a specific geometry that minimizes blanching and thermal damage in skin incisions when used in conjunction with the generator's Advanced Cutting Effect (ACE) mode." The sponsor has now included (AI/SI Supplement) "soft" before tissue and indicated that this device will be used for Prescription Use. This is found adequate.

V. Predicate Device Comparison

The sponsor has identified 2 predicate devices and is claiming substantial equivalence to them, K862221– E-Z Clean Cautery Tip and K960255 –Epitome with ZapGuard. The sponsor has provided a comparison table in their Substantial Equivalence Discussion Section (Section 12, pg 24) discussing the similarities of the device and its predicates in the areas of: intended use, electrode/insulation/coating/guard material, design configurations, sterilization, compatibility, and IEC Testing. The sponsor has provided (AI/SI Supplement, pg 24-26) an updated device comparison table that includes the following areas of electrode comparison: monopolar or bipolar, the shape of each electrode configuration with their appropriate ranges of length and diameter, and the applied energy range. This is found adequate.

VI. Labeling

The sponsor has provided draft package inserts for device that include necessary directions for use, indications for use, safety instructions, warnings, and warranty statements. The sponsor has provided (AI/SI Supplement, pg 32 and 35) at least one compatible Monopolar Electrosurgical Generator and Electrosurgical Accessory and a description of the technological specifications of the Electrosurgical Generator and Electrosurgical Accessory the device may operate with. This is found adequate

VII. Sterilization/Shelf Life/Reuse

The sponsor states the device will be supplied sterile and will be single use. It can be sterilized by radiation, validated by ISO 11137-1, with a dose of 25kGy and SAL level of 10^{-6}. The device can also be sterilized by EtO validated by ISO 11135-1 and ISO 10993-7 with a SAL of 10^{-6}. The device will be packaged in a Tyvek-polyester chevron peel pouch or Multivac Tyvek –Eva-Surlyn-Eva peel pouch.

VIII. Biocompatibility

The sponsor states (Section 15, pg 36) the patient contacting materials are, SS, Polyolefin, PTFE, Vinyl and Silicone. The sponsor states they have conducted biocompatibility testing of the patient contacting materials in conformance to ANSI/AAMI/ISO 10993-1 along with Cytotoxicity, Irritation, and Sensitization Tests. This is found adequate.

IX. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The sponsor has completed electrical testing, per following standards:

Standards	Standard Title
IEC 60601-1:2000	Standard for Safety Medical Electrical Equipment Part 1: General Requirements for Safety
IEC 60601-2-2:2006	Medical Electrical Equipment, Part 2, Particular Requirements for the Safety of High Frequency Surgical Equipment
ANSI/AAMI HF 18:2001	Electrosurgical Devices

The is found adequate.

X. Performance Testing – Bench

The sponsor has completed the following in vitro Performance Testing (pg 37) in conformance to standard ANSI/AAMI HF 18:2001, Electrosurgical Devices:

1- Section 4.1.4.1, Labeling
2- Section 4.2.5.1, Dielectric withstand
3- Section 4.2.5.4, Dielectric withstand of accessories
4-Section 4.3.4, Shipping Temperature
5-Section 4.3.5, Operating Conditions

XI. Performance Testing – Animal

(b) (4)

[redacted]

XII. Performance Testing – Clinical

None Provided

XIII. Substantial Equivalence Discussion

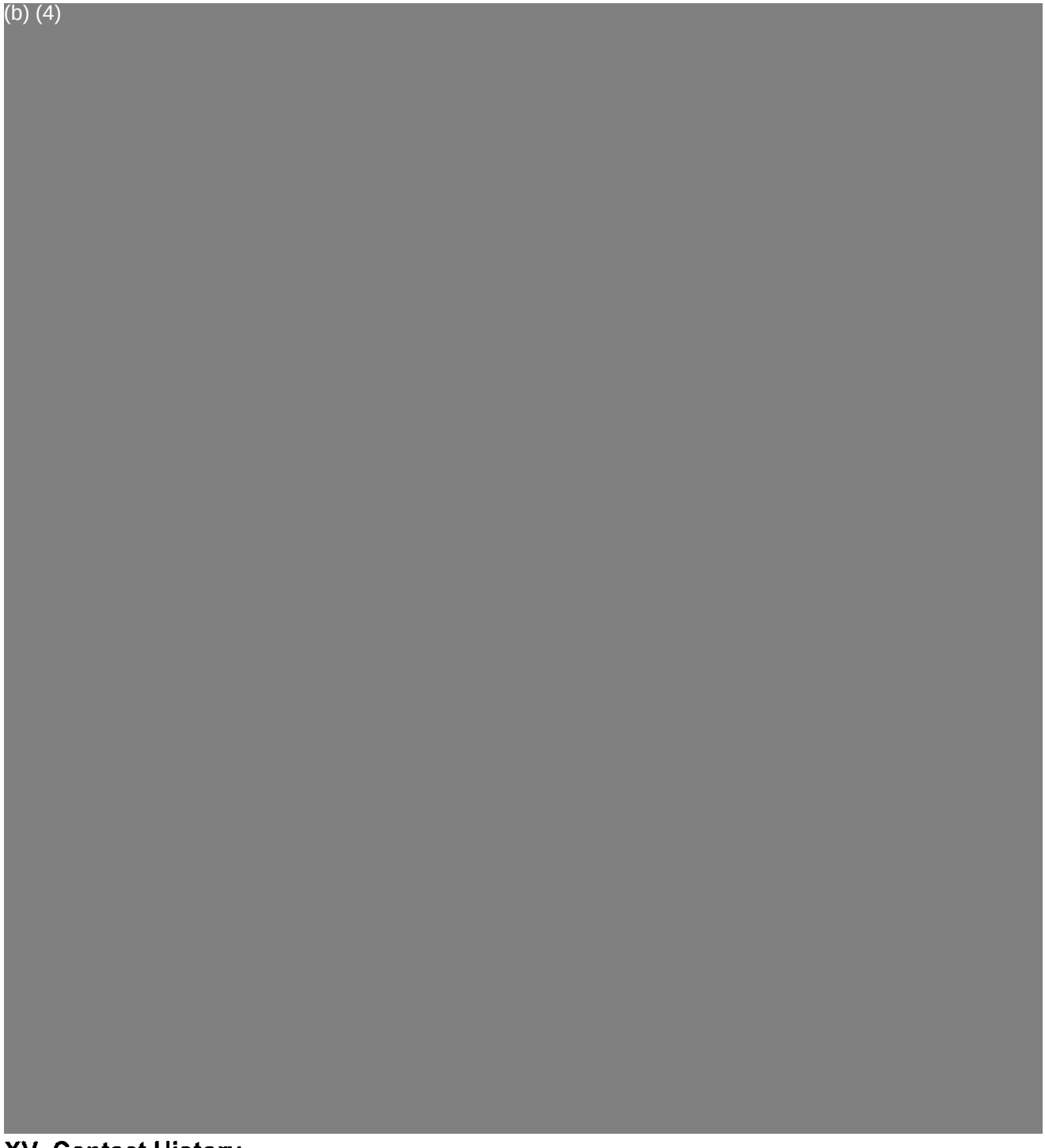
	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	X		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			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?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision: SE

XIV. Responses to Deficiencies

(b)(4)

[redacted]

(b) (4)



XV. Contact History

9/12/2008 – An email sent to the sponsor regarding the request for AI.
9/30/2008 – An email received from sponsor for Compatibility in Labeling.

XVII. Recommendation

Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories

Regulatory Class: Class II
Device Code: GEI

10/15/08

Reviewer
Atiq Chowdhury
Biomedical Engineer
General and Surgical Devices Branch
Division of General, Restorative, and Neurological Devices

Date

I concur with SE.

10/21/08

Branch Chief
Neil Ogden
General and Surgical Devices Branch
Division of General, Restorative, and Neurological Devices

Date

COVER SHEET MEMORANDUM

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

From: Reviewer Name Atiz Chowdhury

Subject: 510(k) Number K081791

To: The Record

Please list CTS decision code AI

☐ 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, Withdrawn, etc.).

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?			
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)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
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)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, 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 Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	Contact OSB.		
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
§78.4400	~~II~~ II	GEI

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

Additional Product Codes:

Review: Neil RP Ogle (Branch Chief) GS DB (Branch Code) 9/12/08 (Date)

Final Review: (Division Director) (Date)

35

Premarket Notification [510(k)] Review
Traditional

K081791

DATE: September 12, 2008
TO: The Record
FROM: Atiq Chowdhury (Biomedical Engineer)

OFFICE: ODE
DIVISION: DGRND

510(K) HOLDER: Megadyne Medical Products
DEVICE NAME: E-Z Clean Electrosurgical Electrode
CONTACT: Ronda K. Magneson, Director of Regulatory Affairs
11506 South State St.
Draper, UT 84020
PHONE: (801)-576-9669
FAX: (801)-576-9698
EMAIL: magneson@megadyne.com

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce the E-Z Clean Electrosurgical Electrode. Under this submission the sponsor is seeking clearance to market this new device for Prescription Use and as a Class II device. The sponsor is being requested additional information regarding following topics and this submission is being put ON HOLD until they provide the requested information.

- Substantial Equivalence – Device Comparison Table
- Labeling – Electrosurgical Generator Compatibility/Accessory
- Revised Indications for Use Page

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)		X	
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

III. 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	

	Yes	No	N/A
Does the device design use software?		X	
Is the device sterile?	X		
Is the device reusable (not reprocessed single use)?		X	
Are "cleaning" instructions included for the end user?			

The device is a monopolar electrosurgical electrode that is coated with polytetraflouroethylene (PTFE). The sponsor states it is intended for general electrosurgical use, and is designed to fit into and work in conjunction with an industry standard hand- or foot-designed activated electrosurgical pencil which is connected to an electrosurgical generator.

The device is available in a number of tip configurations and lengths. Tips such as standard blades, modified blades, needles, blunt needles, and ball-ends. The device also contains the option of a guard or nonsecone on some configurations of blades (5). This nose cone provides additional dielectric protection at the junction where the electrode is connected to the electrosurgical pencil. The sponsor states the device also includes some tip configurations with a specific geometry to enhance the effects of the ACE (Advanced Cutting Effect, cleared ESU K050579) without causing the blanching and thermal damage typically seen with the use of standard electrosurgical electrodes when making skin incisions (See Animal Testing).

IV. Indications for Use

The indication for use as given in the IFU statement (Section 4) is, "E-Z Clean electrosurgical electrodes are intended to conduct radio frequency (RF) current for cutting and coagulation from the RF electrosurgical generator to target soft tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization. Some tip configurations have a specific geometry that minimizes blanching and thermal damage in skin incisions when used in conjunction with the generator's Advanced Cutting Effect (ACE) mode." The second statement regarding the ACE mode has yet to be determined if it is accurate—clinical arm chair consult to be provided.

V. Predicate Device Comparison

The sponsor has identified 2 predicate devices and is claiming substantial equivalence to them, K862221– E-Z Clean Cautery Tip and K960255 –Epitome with ZapGuard. The sponsor has provided a comparison table in their Substantial Equivalence Discussion Section (Section 12, pg 24) discussing the similarities of the device and its predicates in the areas of: intended use, electrode/insulation/coating/guard material, design configurations, sterilization, compatibility, and IEC Testing.

However, the sponsor has is being asked to provide an updated device comparison table that includes the following areas of electrode comparison: monopolar or bipolar, the shape of each electrode configuration with their appropriate ranges of

length and diameter (simply stating same is not sufficient), and the applied energy range.

VI. Labeling

The sponsor has provided draft package inserts for device that include necessary directions for use, indications for use, safety instructions, warnings, and warranty statements. However, the sponsor is being asked to provide at least one compatible Monopolar Electrosurgical Generator and Electrosurgical Accessory or a description of the technological specifications of the Electrosurgical Generator and Electrosurgical Accessory the device may operate with.

VII. Sterilization/Shelf Life/Reuse

The sponsor states the device will be supplied sterile and will be single use. It can be sterilized by radiation, validated by ISO 11137-1, with a dose of 25kGy and SAL level of 10^{-6}. The device can also be sterilized by EtO validated by ISO 11135-1 and ISO 10993-7 with a SAL of 10^{-6}. The device will be packaged in a Tyvek-polyester chevron peel pouch or Multivac Tyvek –Eva-Surlyn-Eva peel pouch.

VIII. Biocompatibility

The sponsor states (Section 15, pg 36) the patient contacting materials are, SS, Polyolefin, PTFE, Vinyl and Silicone. The sponsor states they have conducted biocompatibility testing of the patient contacting materials in conformance to ANSI/AAMI/ISO 10993-1 along with Cytotoxicity, Irritation, and Sensitization Tests. This is found adequate.

IX. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The sponsor has completed electrical testing, per following standards:

Standards	Standard Title
IEC 60601-1:2000	Standard for Safety Medical Electrical Equipment Part 1: General Requirements for Safety
IEC 60601-2-2:2006	Medical Electrical Equipment, Part 2, Particular Requirements for the Safety of High Frequency Surgical Equipment
ANSI/AAMI HF 18:2001	Electrosurgical Devices

The is found adequate.

X. Performance Testing – Bench

The sponsor has completed the following in vitro Performance Testing (pg 37) in conformance to standard ANSI/AAMI HF 18:2001, Electrosurgical Devices:

1- Section 4.1.4.1, Labeling
2- Section 4.2.5.1, Dielectric withstand
3- Section 4.2.5.4, Dielectric withstand of accessories
4-Section 4.3.4, Shipping Temperature

5-Section 4.3.5, Operating Conditions

XI. Performance Testing – Animal

(b) (4)

[redacted]

XII. Performance Testing – Clinical

None Provided

XIII. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?			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?			If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			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?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision: AI

XIV. Deficiencies

(b)(4)

[redacted]

(b) (4)

[redacted]

XV. Contact History

9/12/2008 – An email sent to the sponsor regarding the request for AI.

XVII. Recommendation

I recommend that this submission be placed on hold pending the receipt of the response to the above questions.

9/12/08

Reviewer
Atiq Chowdhury
Biomedical Engineer
General and Surgical Devices Branch
Division of General, Restorative, and Neurological Devices

Date

Branch Chief **Date**
Neil Ogden
General and Surgical Devices Branch
Division of General, Restorative, and Neurological Devices

September 12, 2008

Ronda K. Magneson, Director of Regulatory Affairs
Megadyne Medical Products, Draper, UT
Ph#: (801)-576-9669
Fax#: (801)-576-9698
e-mail: rmagneson@megadyne.com

Re: 510(k) submission – E-Z Clean Electrosurgical Electrode (K081791

Dear Ms. Ronda K. Magneson,

(b) (4)

The subject submission will be placed on hold pending your response with the requested information. If you need more than 30 days to provide a full and complete response, you should submit a request for an extension of time to

Document Mail Center (HFZ 401). For further information on how to apply for an extension and for general 510(k) information, please visit the FDA Website at: http://www.fda.gov/cdrh/devadvice/31435.html#link_6

Sincerely,

Atiq Chowdhury
Biomedical Engineer
(240)276-3805
GSDB/DGRND/ODE/FDA
atiq.chowdhury@fda.hhs.gov

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

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

October 10, 2008

MEGADYNE MEDICAL PRODUCTS, INC.
11506 SOUTH STATE ST.
DRAPER, UTAH 84020
UNITED STATES
ATTN: RONDA K. MAGNESON

510k Number: K081791

Product: E-Z CLEAN ELECTROSURGICAL ELEC

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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

MEGADYNE

K081791/S1

October 9, 2008

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

Attention: Document Control Clerk

K-S

RE: 510(k) Notification (K081791) Additional Information

Megadyne Medical Products, Inc. hereby submits the additional information as requested by Mr. Atiq Chowdhury in his letter dated September 12, 2008.

Included you will find our response letter to Mr. Chowdhury's inquiries and the associated attachments. Please replace the appropriate pages in the original submission with the attached pages in accordance with the page numbering.

The subject of this 510(k) application is a low-risk device that is substantially equivalent to the predicate devices listed and there are no significant questions of safety and efficacy. We hope that you will concur with this conclusion and speedily return a substantially equivalent decision.

Best Regards,

Ronda K. Magneson

Ronda K. Magneson
Director, Regulatory Affairs

MEGADYNE MEDICAL PRODUCTS, INC. • 1506 South State Street • Draper, Utah 84020 USA • Phone: 801-572-6272 • Fax: 801-576-0568 • Toll Free: 800-747-6710 USA

9 October 2008

Atiq Chowdhury
Biomedical Engineer
(240)276-3805
GSDB/DGRND/ODE/FDA
atiq.chowdhury@fda.hhs.gov

Re: 510(k) submission – E-Z Clean Electrosurgical Electrode (K081791)

Dear Mr. Chowdhury:

This letter is in response to your request for clarification on specific items in Megadyne Medical Products' recent 510(k) submission (K081791). The following is in response to your specific requests:

(b) (4)

[redacted]

14

Please reference the attached updated Indications for Use Page (page 10).

I hope this information is sufficient for you to continue your review. If you have further questions or need additional information or clarification, please do not hesitate to contact me directly at 1-801-553-2805.

Sincerely,

Ronda K. Magneson

Ronda K. Magneson
Director, Regulatory Affairs

cc: file

Section 4 Indications for Use Statement

510(k) Number (if known): K081791

Device Name: E-Z Clean electrosurgical electrodes

Indications for use:

E-Z Clean electrosurgical electrodes are intended to conduct radio frequency (RF) current for cutting and coagulation from the RF electrosurgical generator to target soft tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization.

Some tip configurations have a specific geometry that minimizes blanching and thermal damage in skin incisions when used in conjunction with the generator's Advanced Cutting Effect (ACE) mode.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use__√__ OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

D. Device Name

Common Name:	Device, electrosurgical, cutting & coagulation & accessories
Trade Name:	E-Z Clean electrosurgical electrodes
Classification (if known):	21 CFR 878.4400, Electrosurgical cutting and coagulation device and accessories

E. Predicate Devices

The predicate devices include American Medical Products' E-Z Clean Cautery Tip which was cleared for marketing via 510(k) # K862221 by FDA's Office of Device Evaluation on August 11, 1986; and Utah Medical Products' Epitome® Scalpel electrode with ZapGuard™ which was cleared for marketing via 510(k) #K960255 on March 27, 1996.

F. Applicant Device Description

The Megadyne E-Z Clean electrosurgical electrode is a monopolar electrosurgical electrode that is coated with polytetrafluoroethylene (PTFE). It is insulated over the majority of its exposed length. It is intended for general electrosurgical use, and is designed to fit into and work in conjunction with an industry standard hand- or foot-activated electrosurgical pencil which is connected to an electrosurgical unit or ESU. This device is supplied sterile and is not intended to be reused.

The E-Z Clean electrosurgical electrodes are available in a number of tip configurations and lengths. Tips such as standard blades, modified blades, needles, blunt needles, ball-ends, and others are typical.

Some tip configurations (ACE blades) contain a slightly different geometry that will enhance the affects of the generator's Advanced Cutting Effect (ACE) Mode. In this mode, the blade will make skin incisions without the blanching or thermal damage commonly seen with standard electrosurgery. The new E-Z Clean ACE Blade provides a wound site that will heal similar to a scalpel wound (comparable Histopathology) when used in conjunction with the ACE mode. When not being used to perform skin incisions the ACE Blade functions as a standard E-Z Clean blade in all cutting and coagulating modes.

This submission also includes the option of a guard or nosecone on some configurations of electrodes. This nose cone provides additional dielectric protection at the junction where the E-Z Clean electrosurgical electrode is connected to an electrosurgical pencil.

G. Applicant Device Intended Use

E-Z Clean electrosurgical electrodes are intended to conduct radio frequency (RF) current for cutting and coagulation from the electrosurgical generator to target soft

tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization.

Some tip configurations have a specific geometry that minimizes blanching and thermal damage in skin incisions when used in conjunction with the generator's Advanced Cutting Effect (ACE) mode.

H. Technological Characteristics

The proposed device shares the same technological characteristics found in the predicate devices. It is an electrosurgical electrode intended for electrosurgical cutting and coagulation.

I. Safety information

Questions of safety and effectiveness are the same for this device as they are for the predicate devices and other electrosurgical electrodes on the market. There are no new technologies incorporated into the device.

Megadyne has conducted extensive testing to ensure conformance to the voluntary standard ISO 60601-2-2:2006, *Medical electrical equipment, Part 2: Particular requirements for the safety of high frequency surgical equipment,* and ANSI / AAMI HF 18-2001, *Electrosurgical Devices.*

Catalog Number	*Description*
ACE 0012	ACE flat blade electrode, 2.5"
ACE 0012A	ACE flat blade electrode, 2.75"
0012AMD	E-Z Clean flat blade electrode, 2.75", modified, with nose cone
0012MD	E-Z Clean flat blade electrode, 2.5", modified, with nose cone
0013	E-Z Clean needle electrode, 2.75"
0013M	E-Z Clean needle electrode, 2.75", modified
0013MD	E-Z Clean needle electrode, 2.75", modified, with nose cone
0014	E-Z Clean flat blade electrode, 6.5"
0014A	E-Z Clean flat blade electrode, 4"
0014AM	E-Z Clean flat blade electrode, 4", modified
0014M	E-Z Clean flat blade electrode, 6.5", modified
0014AMD	E-Z Clean flat blade electrode, 4", modified, with nose cone
0014MD	E-Z Clean flat blade electrode, 6.5", modified, with nose cone
0015	E-Z Clean ball electrode, 2"
0016	E-Z Clean needle electrode, 6"
0016A	E-Z Clean needle electrode, 4", step-down
0016AM	E-Z Clean needle electrode, 4", step-down, modified
0016M	E-Z Clean needle electrode, 6", modified
0028	E-Z Clean needle electrode, 5.75", bayonet
0028M	E-Z Clean needle electrode, 5.75", bayonet, modified
0029	E-Z Clean Flat Blade electrode, 6.25", bayonet
0029M	E-Z Clean Flat Blade electrode, 6.25", bayonet, modified
0066	E-Z Clean flat blade electrode, 2.5", All-in-One
0113A	E-Z Clean needle electrode, 4.5", blunt needle
C117	E-Z Clean flat blade electrode, 12cm
C117M	E-Z Clean flat blade electrode, 12cm, modified
0118	E-Z Clean, Sharp Needle, 2"
0118A	E-Z Clean, Sharp Needle, 2.5"
0113	E-Z Clean, Blunt Needle, 2.75"
0113M	E-Z Clean, Blunt Needle, 2.75", modified
0119	E-Z Clean MEGAfine 45 degree Needle
0119A	E-Z Clean MEGAfine 45 degree Needle, 3mm
0120	E-Z Clean MEGAfine 90 degree Needle
0121	E-Z Clean MEGAfine Needle Electrode, 6.5"

Sample drawings of the proposed device, including packaging configuration, are provided in Appendix A of this submission.

A. Device Intended Use

E-Z Clean electrosurgical electrodes are intended to conduct radio frequency (RF) current for cutting and coagulation from the electrosurgical generator to target soft tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization. The device is intended for single use; it is not intended to be cleaned or reused.

Some tip configurations have a specific geometry that minimizes blanching and thermal damage in skin incisions when used in conjunction with the generator's Advanced Cutting Effect (ACE) mode.

Section 12 Substantial Equivalence Discussion

This device is substantially equivalent to the American Medical Products' E-Z Clean Cautery Tip (K862221) and Utah Medical Products' Epitome® Scalpel electrode with ZapGuard™ (K960255). Listed below is a comparison of the features of the proposed device and the predicate devices.

A. Comparison table of the proposed device and the predicate devices

Component/ Feature	Proposed Device	Predicate Device: E-Z Clean Cautery Tip (K862221)	Predicate Device: Epitome with ZapGuard (K960255)
Intended use	to be used in any application which requires monopolar electrosurgical cutting or coagulation	to be used in any application which requires monopolar electrosurgical cutting or coagulation	for use in virtually every surgical discipline where flat, paddle-type ES blades are used for making straight cuts through tissue.
Electrode Material	300 series stainless steel	300 series stainless steel	Stainless Steel, Ceramic, and tungsten wire
Insulation Material	Polyolefin and PTFE	Polyolefin	Polyolefin
Coating Material	PTFE	PTFE	none
Guard Material	Silicone	none	Silicone
Configurations available			
Blade Electrode			
Lengths Diameter	2" to 6.5" Standard 3/32" shaft	2" to 6.5" Standard 3/32" shaft	2.36" to 6.33" Standard 3/32" shaft
Ball Electrode			
Lengths Diameter	2" to 5" Standard 3/32" shaft	2" to 5" Standard 3/32" shaft	N/A
Needle Electrode			
Lengths Diameter	(Sharp, Fine, Blunt) 2" to 6.5" Standard 3/32" shaft	(Sharp, Fine, Blunt) 2" to 6.5" Standard 3/32" shaft	N/A
Sterilization	Radiation – Gamma EO	Radiation – Gamma	EO

Component/ Feature	Proposed Device	Predicate Device: E-Z Clean Cautery Tip (K862221)	Predicate Device: Epitome with ZapGuard (K960255)
Compatibility	May be used with any monopolar ESU and ES pen that accepts 3/32" diameter electrodes	May be used with any monopolar ESU and ES pen that accepts 3/32" diameter electrodes	May be used with any ESU and ES pen that accepts 3/32" diameter electrodes
Single use	Yes	Yes	Yes
Rated Accessory Voltage	≤10.8 kV	≤10.8 kV	Limited to Max Power Cut/Coag 150 Watts Spray Coag 120 Watts (2 sec max bursts, w/min 2 sec between bursts) Continuous 60 Watts
Conforms with IEC 60601-2-2	yes	yes	yes
Intended use	to be used in any application which requires electrosurgical cutting or coagulation	same	same
Electrode Material	300 series stainless steel	same	Stainless Steel, Ceramic, and tungsten wire
Insulation Material	Polyolefin and PTFE	Polyolefin	Polyolefin
Coating Material	PTFE	PTFE	none
Guard Material	Silicone	none	Silicone
Configurations available	Various including blade, needle, and ball end electrodes	same	Blade
Sterilization	Radiation – Gamma EO	Radiation - Gamma	EO
Compatibility	Standard 3/32" shaft	same	same
Single use	yes	same	same

Component/ Feature	Proposed Device	Predicate Device: E-Z Clean Cautery Tip (K862231)	Predicate Device: Epitome with ZapGuard (K960255)
Conforms with IEC 60601-2-2	yes	same	same

B. Discussion of similarities

The proposed device is similar to the predicate devices in configuration, intended use, technology, performance, and operation principle.

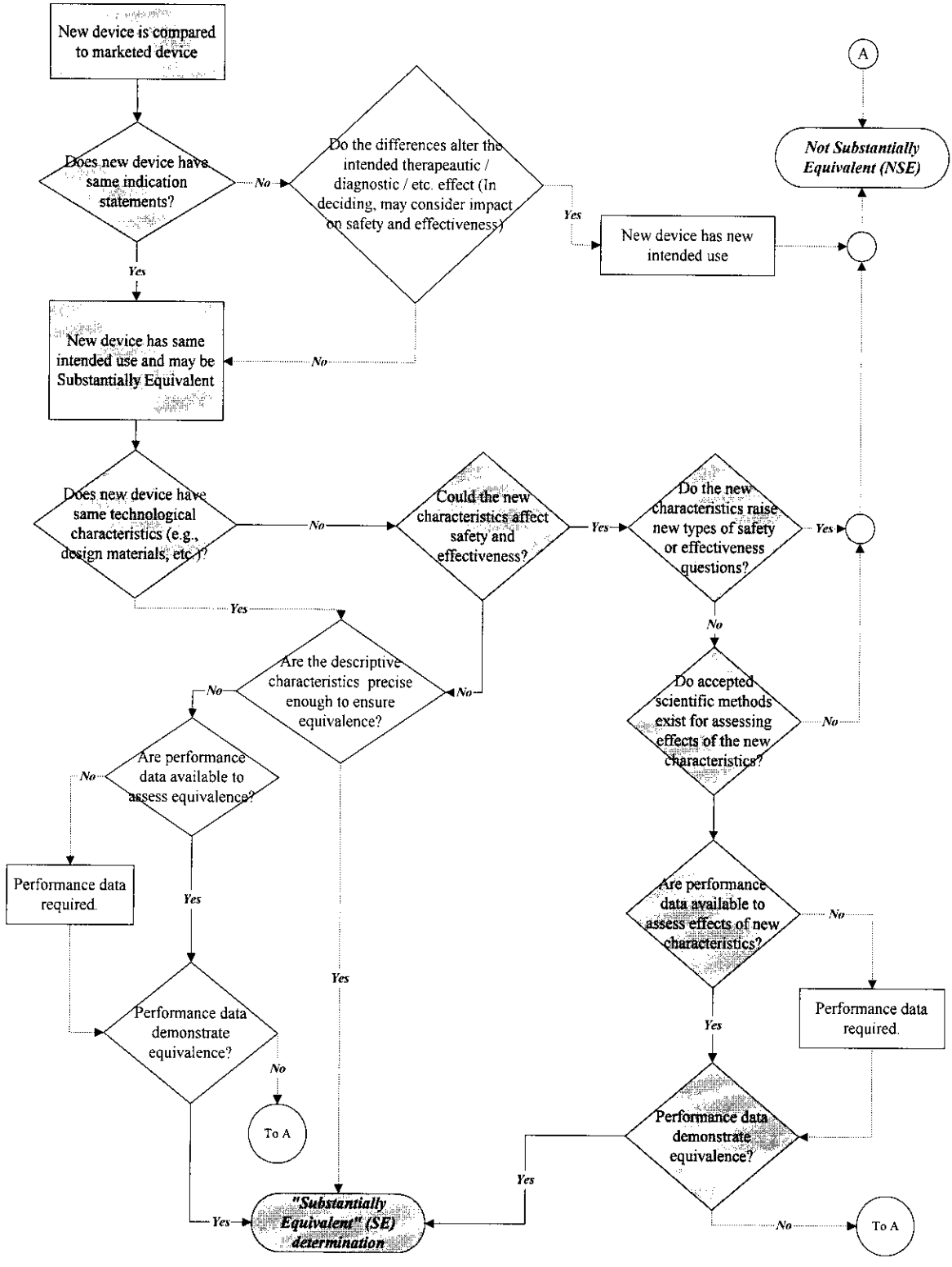
C. Discussion of differences

The only difference as identified in the table above is the insulating material used on certain configurations of the Megadyne electrode is a combination of polyolefin and PTFE, whereas the material used on the predicate device is polyolefin. The PTFE material was selected for some modified configurations as a more durable material than polyolefin.

The addition of PTFE insulation is an insignificant change that does not require the submission of a new 510(k) according to the FDA guidance document *Deciding When to Submit a 510(k) for a Change to an Existing Device*, dated January 10, 1997, since the material is biocompatible, and provides sufficient insulation strength to meet the requirements of ANSI / AAMI HF18-2001.

D. Substantial Equivalence Decision-Making Process Flowchart

The 510(k) Substantial Equivalence Decision-Making Process Flowchart used by ODE in evaluating 510(k) notifications follows, with the applicable decision points highlighted in gray and explained in the table following the chart.



Decision-Making Process Flowchart step	**Answer**	**Remarks**
New Device Is Compared To Predicate Device	Yes	The proposed device is substantially equivalent to Megadyne Medical Products' E-Z Clean Cautery Tip (K862221) and Utah Medical Products' Epitome® Scalpel electrode with ZapGuard™ (K960255).
Does New Device Have Same Indication Statements?	Yes	The new device has the same indication statement as the predicate device. Ref. "Indication for Use" statement, Section 4.
New Device Has Same Indication Statements And May Be "Substantially Equivalent"		
Does New Device Have Same Technological Characteristics (e.g., Design, Materials, Etc.)?	No	The proposed device shares the same technological characteristics found in the predicate devices but utilizes different materials. Ref. Section 12, Substantial Equivalence Discussion.
Could The New Characteristics Affect Safety Or Effectiveness?	Yes	The changes which are the subject of this 510(k) involve material changes. Those changes require examination of the impact, if any, on the device safety or effectiveness.
Do the characteristics raise new types of safety or effectiveness questions?	No	The differences are discussed in Section 12 entitled "Substantial Equivalence Comparison". The differences do not raise any new types of safety or effectiveness questions.
Do accepted scientific methods exist for assessing effects of the new characteristics?	Yes	Industry Standards exist and testing of the proposed device ensures conformance with these standards. Ref. Sections 9, Declaration of Conformance and Section18, Performance Testing.

Decision-Making Process Flowchart step	**Answer**	**Remarks**
Are performance data available to assess effects of new characteristics?	Yes	Megadyne certifies that performance data is available and the device conforms to the applicable standards. Ref. Section 9, Declarations of Conformance, Section 15, Biocompatability, and Section 18, Performance Testing - Bench.
Performance Data Demonstrate Equivalence?	Yes	Performance data demonstrates substantial equivalence. The changes do not affect the safety and effectiveness of the device. Ref. Section 9, Declarations of Conformance, Section 15, Biocompatability, and Section 18, Performance Testing - Bench..
"Substantially Equivalent" Determination		The device is substantially equivalent to the predicate device.

Section 13 Proposed Labeling

Labeling for the E-Z Clean electrosurgical electrodes consists of the pouch label, box label, and the accompanying Instructions for Use (IFU). Advertising literature is undetermined at this point. All labels will be developed in accordance with Megadyne's standard label control and approval procedures.

Examples of the proposed device draft labeling follow in this section. A sample of the predicate device IFUs are provided in Appendix B.

A. Box Labels

Figure D below illustrates the box label for devices that are sterilized by exposure to Gamma radiation.

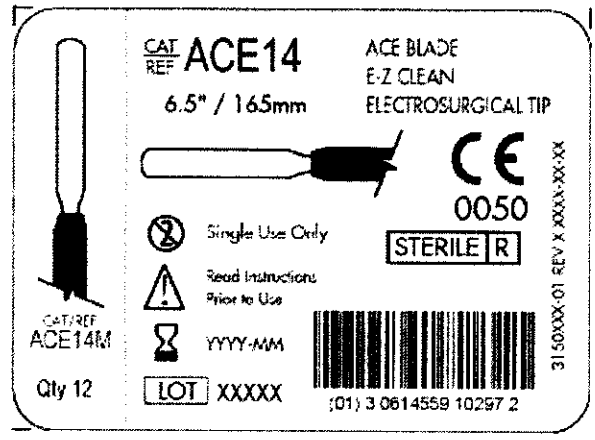


Figure D

Figure E below illustrates the box label for devices that are sterilized by exposure to Ethylene Oxide.

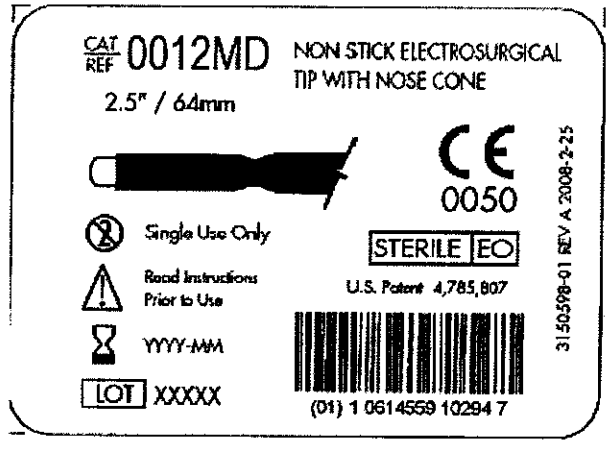


Figure E

B. Unit Labels

Figure F below illustrates a typical unit label for devices that are sterilized by exposure to Gamma radiation.

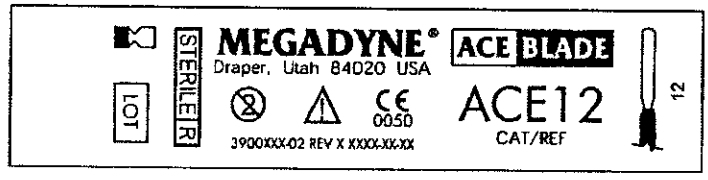


Figure F

Figure G below illustrates a typical unit label for devices that are sterilized by exposure to Ethylene Oxide.

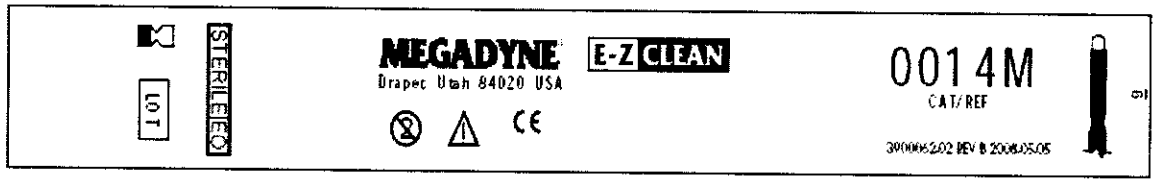


Figure G

C. Device Instructions for Use

The following additions to the Instructions for Use are proposed as highlighted in yellow:

The following illustrates the Instructions for Use for the E-Z Clean electrosurgical electrodes with and without the nose cone.

MEGADYNE®
11506 SOUTH STATE STREET
DRAPER, UTAH 84020 USA
Phone: +1 (801) 576-9669 +1 (800) 747-6110 (USA)
Fax: +1 (801) 576-9698 +1 (888) 747-8774 (USA)

E-Z CLEAN Electrosurgical Electrodes

E-Z CLEAN electrosurgical electrodes are intended to conduct radio frequency (RF) current for monopolar cutting and coagulation from the RF electrosurgical generator to target soft tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization.

INSTRUCTIONS FOR USE

E-Z CLEAN electrosurgical electrodes are coated with PTFE to reduce eschar buildup and aid in the easy removal of eschar with a damp gauze or sponge.

E-Z CLEAN electrosurgical electrodes are designed to fit most electrosurgical pencils and other electrosurgical accessories. Prior to use, ensure the electrode has the proper compatibility and fit with the accessory.

To place the E-Z CLEAN Electrosurgical electrodes into an electrosurgical accessory:

1. Ensure the accessory is not connected to the generator.
2. Fully insert the electrode into the accessory. Make sure the insulating sleeve fits securely inside the accessory. If the electrode is equipped with a protective nose cone make sure the electrode fully seats in the pencil.
3. If the insulating sleeve does not fit securely inside the accessory, do not use the electrode.
4. Some electrodes are supplied with a tip protector. If a tip protector is present, remove prior to use.

WARNINGS

- **When not in use, store active electrodes in an electrically insulated container.**
- **If the E-Z CLEAN electrosurgical electrode is equipped with a protective nosecone. Do not remove the nosecone.**
- **Electrosurgical electrodes that are activated or hot from use can cause a fire; do not place them near or in contact with flammable materials and substances (e.g. drapes, flammable gases, endotracheal tubes, etc).**
- **Electrosurgery should not be used to perform circumcisions.**
- **Use the lowest possible power settings to achieve the desired effect.**

CAUTIONS

- **These devices are intended for single use only. Properly discard after use. Do not resterilize.**
- **E-Z CLEAN blade electrodes can be bent up to approximately 60°. The use of instruments to modify the electrode and / or excessive bending may damage the coating or the electrode.**
- **Do not use a scratch pad or other abrasive cleaner to remove eschar. This may damage the PTFE coating.**
- **If the electrode or coating is damaged discard the electrode.**
- **Refer to the generator manufacturer's operating manual for proper usage of electrosurgical generator(s).**
- **Activate electrodes when in contact, or in close proximity to target tissue to avoid the possibility of unintended tissue damage.**
- **Federal (USA) law restricts this device to sale by or on the order of a physician.**

Compatibility

Megadyne recommends use of E-Z Clean electrodes with the MegaPower Electrosurgical Generator and Megadyne accessory devices (i.e. electrosurgical pencils and return electrodes). These electrodes have been tested and are approved for use at a maximum power setting of 300 watts, a maximum voltage of ≤10.8 kV, and a maximum frequency of 510 kHz.

STERILE EO R

Below illustrates the Instructions for Use for the ACE Blade electrosurgical electrode:

MEGADYNE®
11506 SOUTH STATE STREET
DRAPER, UTAH 84020 USA
Phone: +1 (801) 576-9669 +1 (800) 747-6110 (USA)
Fax: +1 (801) 576-9698 +1 (888) 747-8774 (USA)

ACE BLADE Electrosurgical Tips

E-Z Clean electrosurgical electrodes are intended to conduct radio frequency (RF) current for monopolar cutting and coagulation from the RF electrosurgical generator to target soft tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization.

Some tip configurations have a specific geometry that minimizes blanching and thermal damage in skin incisions when used in conjunction with the generator's Advanced Cutting Effect (ACE) mode.

Megadyne recommends clinicians familiarize themselves with the performance of the ACE Blade and ACE mode combination by practicing their technique on appropriate tissue simulations to determine the anticipated scalpel-like cutting characteristics.

INSTRUCTIONS FOR USE

1. The ACE blade in ACE Mode can be used at any stage of a surgical procedure to dissect tissue where little to no thermal damage is desired. The ACE blade can be used as a standard electrosurgical blade in coagulate modes or blended modes during the procedure, alleviating the need to change electrosurgical blades.
2. ACE BLADE Electrosurgical tips are coated with PTFE to reduce eschar buildup and aid the easy removal of eschar with a damp gauze or sponge
3. ACE BLADE Electrosurgical tips are designed to fit most electrosurgical pencils and other electrosurgical accessories. Prior to use, ensure the electrode has the proper compatibility and fit with the accessory.
4. To use ACE Blade for scalpel-like effect, place generator in ACE Mode.
5. Incisions may be made using a single pass technique or multiple passes.
6. Cutting with the ACE blade requires very little downward pressure to penetrate the skin and relatively little pressure when compared to a cold scalpel.
7. Each pass should be made using a determined stroke not pausing at any point in the course of the incision. Moving slowly through the tissue does not increase the cutting ability of the ACE blade and may cause thermal damage.
8. For skin incisions, prior to making contact activate the ACE Mode by pressing the yellow cut button on the pencil.

To place the ACE BLADE Electrosurgical tips into an electrosurgical accessory:

1. Ensure the accessory is not connected to the generator.
2. Fully insert the electrode into the accessory. Make sure the insulating sleeve fits securely inside the accessory.
3. If the insulating sleeve does not fit securely inside the accessory, do not use the electrode.
4. Some electrodes are supplied with a tip protector. If a tip protector is present, remove prior to use.

WARNINGS

- **When not in use, store active electrodes in an electrically insulated container.**
- **Electrosurgical tips that are activated or hot from use can cause a fire; do not place them near or in contact with flammable materials and substances (e.g. drapes, flammable gases, endotracheal tubes, etc).**
- **Electrosurgery should not be used to perform circumcisions.**
- **Use the lowest possible power settings to achieve the desired effect.**

CAUTIONS

- **These devices are intended for single use only. Properly discard after use. Do not resterilize.**
- **ACE BLADE Electrosurgical tips can be bent up to approximately 60°. The use of instruments to modify the electrode and / or excessive bending may damage the coating or the electrode.**
- **Do not use a scratch pad or other abrasive cleaner to remove eschar. This may damage the PTFE coating.**
- **If the electrode or coating is damaged discard the electrode.**
- **Refer to the generator manufacturer's operating manual for proper usage of electrosurgical generator(s).**
- **For non-skin incisions, activate the electrodes when in contact, or in close proximity to target tissue to avoid the possibility of unintended tissue damage.**
- **Moving slowly through the tissue does not increase the cutting ability of the ACE blade and may deliver excessive energy to surrounding tissues causing unwanted thermal damage to the incision edges.**
- **Federal (USA) law restricts this device to sale by or on the order of a physician.**

RF voltage rating
≤10.8 kV, consult electrosurgical generator specifications

Compatibility
Megadyne recommends use of the ACE BLADE with the Mega Power ™ Electrosurgical Generator and Megadyne accessory devices (i.e. electrosurgical pencils and return electrodes).

STERILE EO R