Records Processed under FOIA Request # 2015-7673; Released by CDRH on 10-8-2015

K971158

REDACTED BY MFR

July 31, 1997

Freedom of Information Staff, HFZ-82
Center for Devices and Radiological Health, FDA
2098 Gaither Road
Rockville, MD 20850

This is our response to the Predisclosure Notification (PDN) you sent to us postmarked 7/28/97.

Enclosed per your request, is a copy of our 510(k) submission number: K971758 which has been approved by FDA/CDRH and marked up according to your instructions.

Reference:

510(k) Number:	K971758
Trade Name:	Cauterization Smoke Evacuator
Regulatory Class:	II
Product Code:	GEI
Dated:	May 10, 1997
Received FDA:	May 13, 1997
Approved FDA:	July 21, 1997

If you have any questions, please contact me by telephone or FAX.

Sincerely,

Thomas W. Parkinson
Leader - Quality Assurance / Regulatory Affairs

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
15653 Neo Parkway • Cleveland, Ohio 44128 • Phone: (216) 475-5577 • Fax: (216) 475-5575

Records Processed under FOIA Request # 2015-7673; Released by CDRH on 10-8-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

IMPORTANT PREDISCLOSURE NOTIFICATION (PDN)
REPLY REQUESTED WITHIN FIVE DAYS OF RECEIPT

The Food and Drug Administration (FDA) is requesting that you review your cleared 510(k) submission, and submit to FDA a copy of the 510(k) indicating which portions you believe are exempt from release under the Freedom of Information Act. If you submitted a 510(k) Statement with your 510(k) submission, the copy of the 510(k) we are now requesting is the same type copy you are required to make available, under 21 CFR 807.93(c). (Please see the attachment for the types of information that may be deleted from your records prior to disclosure).

If you do not respond and we receive a Freedom of Information (FOI) request, the FOI regulation will provide you with five working days in which to respond to FDA. If we do not receive a response, we will release the records following review of the 510(k), by the Center for Devices and Radiological Health's Freedom of Information Staff. If you need additional time to review the 510(k), please telephone this office at (301) 594-4774 ext. 300 or fax (301) 594-4792. **Mail your written response to :**

Freedom of Information Staff, HFZ-82
Center for Devices and Radiological Health, FDA
2098 Gaither Road
Rockville, Maryland 20850

The PDN is required under Executive Order 12600 (June 23, 1987) and by FDA's Public Information Regulation (21 CFR 20.61) A claim of confidentiality must be justified and is subject to the False Reports to Government Act (18 USC 1001).

Attachment

15 May 97

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

Records Processed under FOIA Request # 2015-7673; Released by CDRH on 10-8-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Thomas W. Parkinson
Leader-Quality Assurance/Regulatory Affairs
Applied Medical Technology, Inc.
15653 Neo Parkway
Cleveland, Ohio 44128

JUL 21 1997

Re: K971758
Trade Name: Cauterization Smoke Evacuator
Regulatory Class: II
Product Code: GEI
Dated: May 10, 1997
Received: May 13, 1997

Dear Mr. Parkinson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

Records Processed under FOIA Request # 2015-7673; Released by CDRH on 10-8-2015

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

4

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

Records Processed under FOIA Request # 2015-7673; Released by CDRH on 10-8-2015

K971758

SECTION - I

I.5. - INDICATIONS FOR USE STATEMENT

The Cauterization Smoke Evacuator is an accessory device used to provide an air suction path for the reduction of gasses, body fluids, and smoke associated with the use of most electro-cauterization systems. The Cauterization Smoke Evacuator is meant to be an accessory add-on device to currently designed and distributed electro-cauterization systems, and most standard operating room suction systems.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971758

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

Records Processed under FOIA Request # 2015-7673; Released by CDRH on 10-8-2015

Cauterization Smoke Evacuator

510(k)

K971758

Applied Medical Technology, Inc.
15653 Neo Parkway
Cleveland, OH 44128-3150

May 10, 1997

SECTIONS CONSIDERED TO BE TRADE SECRET, PROCESS SECRETS, ETC HAVE BEEN BLACKED OUT 7-31-97 AMT

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

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SECTION A - TABLE OF CONTENTS

Applied Medical Technology, Inc.

Cauterization Smoke Evacuator

SECTION and DESCRIPTION		PAGE(S)
Cover Letter		--
Title Page		--
A.	**Table of Contents (Revised June 24, 1997)**	**A.1. through A.3.**
B.	Letter of Notification	B.1.
C.	Confidentiality Statement	C.1.
D.	General Information	D.1.
	D.a. Device Name)trade or proprietary name and common or usual name)	
	D.b. Classification Name	
	D.c. Establishment Registration Number	
	D.d. Address of the Manufacturing Facility & Sterilization Site	
	D.e. Classification of the Device	
	D.f. Performance Standards	
	D.g. Reason for premarket notification	
E.	Substantial Equivalency Information	
	E.a. Statement of Substantial Equivalency	E.1.
	E.b. Product Comparison Charts	E.2. and E.3.
	E.c. Marketing Materials	E.4. through E.7.
F.	Premarket Notification Truthful and Accurate Statement	F.1.
G.	Safety and Effectiveness Statement	G.1.
H.	510(k) Summary/Statement Certification	H.1.

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

Records Processed under FOIA Request # 2015-7673; Released by CDRH on 10-8-2015

SECTION A - TABLE OF CONTENTS - continued

I.	Labeling Information		
	I.a.	Draft Packaging Labels with Text	I.1. and I.2.
	I.b.	**Draft Instructions For Use (Revised June 24, 1997)**	**I.3. and I.4.**
	I.c.	Draft Promotional Material	I.5.
	I.d.	Intended Use Statement	I.6.
	I.e.	Indications for Use Statement	I.7.
J.	Device Description and Drawings		
	J.a.	Device Description	J.1.
	J.b.	**Drawing (Added Drawing pg. J.3. - June 24, 1997)**	**J.2. and J.3.**
K.	Materials and Testing		
	K.a.	List of Materials Used	K.1.
	K.b.	Biocompatibility Information/Data	K.2.
L.	Performance Data to determine Equivalence		L.1.
M.	Sterility Information		M.1.
	M.a.	Method	
	M.b.	SAL	
	M.c.	Method of Validation of Sterilization Cycle	
	M.d.	Residual Levels of EtO, EtCh, EtG	
	M.e.	Packaging Description (including materials)	
	M.f.	Non-Pyrogenic Information	
N.	Software Validation Statement		N.1.
O.	Kit information		
	O.1.	Kit Contents	O.1.
	O.2.	Kit Certification Statement	O.2.

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

Records Processed under FOIA Request # 2015-7673; Released by CDRH on 10-8-2015

SECTION A - TABLE OF CONTENTS - continued

Addendum Attachments:

Polyurethane Tubing:

(b) (4) [redacted]

Adapter is purchased: Qosina Enteral Adapter part number 41410.

4 Pages: Qosina Corporation
150-Q Executive Drive
Edgwood, NY 11717-8329

Part 41410 - Enteral Adapter
Drawing, 1 Page
Molded using ABS, Sinkral M22-1719
Technical Data Sheet, 3 Pages

Adhesive is purchased: (b) (4) [redacted]

(b) (4) [redacted]

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

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Food and Drug Administration
Bureau of Medical Devices
Document Mail Center (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

May 10, 1997

Reference: **510(k) Letter of Notification**

Attention: Document Control Clerk

In accordance with section 510(k) of the Federal Food, Drug, and Cosmetic Act, and in conformance with 21 C.F.R. 807, this pre-market notification is being submitted in advance to an eventual introduction of this device for commercial distribution. We would appreciate your earliest attention to this 510(k) submission. If you need more information, please feel free to contact me at telephone number: (216) 475-5577, or by FAX at: (216) 475-5575.

Company Name: Applied Medical Technology, Inc.
15653 Neo Parkway
Cleveland, OH 44128-3150

Phone Number: 216-475-5577

Fax Number: 216-475-5575

Contact Person: Thomas W. Parkinson - Quality Assurance/Regulatory Affairs

Signature: Thomas W Parkinson Date: May 10, 1997

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

Records Processed under FOIA Request # 2015-7673; Released by CDRH on 10-8-2015

SECTION - C

CONFIDENTIALITY STATEMENT

Applied Medical Technology, Inc. requests that the Food and Drug Administration hold as confidential information on our intent to market this device. We consider our intent to market this device to be confidential commercial information, and, therefore exempt from public disclosure. To the best of our knowledge, neither I nor anyone else associated with Applied Medical Technology, Inc., has disclosed through advertising nor any other manner our intent to market the device to scientists, market analysts, exporters, or other individuals, except employees, or paid consultants to, our company or individuals in an advertising or law firm pursuant of commercial arrangements with appropriate safeguards for secrecy. We have taken precautions to protect the confidentiality of the intent to market the device. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 331(q).

We would appreciate your earliest attention to this 510(k) submission. Please feel free to contact me at telephone number:(216) 475-5577, or FAX number: (216) 475-5575, if you have any questions or require any further information concerning this submission.

Sincerely,

Thomas W Parkinson

Thomas W. Parkinson
Quality Assurance / Regulatory Affairs

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

Records Processed under FOIA Request # 2015-7673; Released by CDRH on 10-8-2015

SECTION - D

GENERAL INFORMATION

D.a. Common Name:	Cauterization Smoke Evacuator
D.b. Classification Name:	Electrosurgical cutting and coagulation device and accessories.
Regulation:	878.4400
D.c. Establishment Registration Number:	1526012
D.d. Manufacturing Facility:	Applied Medical Technology, Inc. 15653 Neo Parkway Cleveland, OH 44128-3150
Sterilization Site:	Medical Manufacturing Corp 2205 East 33rd Street Erie, PA 16510-2555 Registration Number 2528981
D.e. Classification:	Class II
D.f. Performance Standards:	None established under Section 514.
D.g. Reason for premarket notification:	New device.

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

Records Processed under FOIA Request # 2015-7673; Released by CDRH on 10-8-2015

SECTION - E

E.a. - SUBSTANTIAL EQUIVALENCY STATEMENT

This device is substantially equivalent to currently marketed devices offered by other medical device manufacturing companies.

The two companies used for comparison that distribute a substantially equivalent item are:

Implantech Associates, Inc.
2264 Eastman Ave. - Unit 101
Ventura, CA 93003

Phone: 800-733-0833
FAX: 805-339-9414

BioPlexius Corporation
3753 Howard Hughes Parkway - Suite 310
Las Vegas, NV 89109

Phone: 702-369-5971
FAX: 702-369-2607

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

Records Processed under FOIA Request # 2015-7673; Released by CDRH on 10-8-2015

SECTION - E

E.b. - PRODUCT COMPARISON CHARTS

Chart #1

Applied Medical Technology, Inc. - Cauterization Smoke Evacuator

-vs-

Implantech™ Associates, Inc. - SE-100 Smoke Aspiration Tip

	AMT	Implantech™ Associates, Inc.
Intended Use:	Electro - Cauterization accessory to evacuate Smoke, Particles, and Body Fluids.	Electro - Cauterization accessory to evacuate Smoke, Particles, and Body Fluids.
Design:	Length of flexible tubing to attach over the end (slip fit) of an electro-cauterization tip. A band is supplied to assist in securing the device to the electro-cauterization pencil. A length of tubing and adapter is attached to provide connection to most wall suction systems. Universally adaptable.	Length of flexible tubing to slip fit with bead straps to help secure it to an electro-cauterization pencil tip. A length of tubing to connect to most wall suction systems. Universally adaptable.
Sizes:	One size fits most known electro-cauterization pencils. Can be trimmed to length. Sterile packaged for single use and disposable. Ten units per box.	One size. Can be trimmed to length. Sterile packaged and disposable. Twenty-Five units per box.
Materials:	(b) (4) [redacted]	Clear tubing.
Manufacturing Method:	Injection molded or extruded and assembled.	Injection molded, extruded, and assembled.
Features:	No maintenance, easy to use.	No maintenance, easy to use.
Target Users:	Surgeons using an electro-cauterization device.	Surgeons using an electro-cauterization device.
Performance:	The Applied Medical Technology, Inc. Cauterization Smoke Evacuator performance can be expected to be equivalent to the Implantech Associates, Inc. SE-100.	The SE-100 smoke aspiration tip provides simple, effective protection for you and your team by removing smoke, particles and body fluids from the surgical site.

Implantech™ Associates, Inc.
2264 Eastman Avenue - Unit 101
Ventura, CA 93003

Phone: 800-733-0833 805-339-9415 FAX: 805-339-9414

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

Records Processed under FOIA Request # 2015-7673; Released by CDRH on 10-8-2015

SECTION - E

Chart #2

Applied Medical Technology, Inc. - Cauterization Smoke Evacuator
-vs-
BioPlexus Corp. - Aspiration Tip

	AMT	BioPlexus Corp.
Intended Use:	Electro - Cauterization accessory to evacuate Smoke, Particles, and Body Fluids.	Electro - Cauterization accessory to evacuate Smoke and Body Fluids during surgical procedures
Design:	Length of flexible tubing to attach over the end (slip fit) of an electro-cauterization tip. A band is supplied to assist in securing the device to the electro-cauterization pencil. A length of tubing and adapter is attached to provide connection to most wall suction systems. Universally adaptable.	Patented design. Length of flexible bi-lumen style flexible tubing to attach it to an electro-cauterization pencil tip. A length of built-in tubing to connect to most wall suction systems. Universally adaptable.
Sizes:	One size fits most known electro-cauterization pencils. Can be trimmed to length. Sterile packaged for single use and disposable. Ten units per box.	One size. Fits a wide variety of electrocautery knives. Can be trimmed to accommodate most blades. Supplied sterile packaged single. Ten units per box.
Materials:	(b) (4) [redacted]	Translucent for visual identification of particle and bodily fluid transfer.
Manufacturing Method:	Injection molded or extruded and assembled.	Injection molded, extruded, and assembled.
Features:	No maintenance, easy to use.	No maintenance, easy to use.
Target Users:	Surgeons using an electro-cauterization device.	Surgeons using an electro-cauterization device.
Performance:	The Applied Medical Technology, Inc. Cauterization Smoke Evacuator performance can be expected to be equivalent to the BioPlexus Aspiration Tip.	The BioPlexus Aspiration Tip smoke aspiration tip provides simple, effective protection for you and your team by removing smoke, particles and body fluids from the surgical site. Removes fluids, debris, smoke plumes, and odors. Improves vision to the operative field and surgical facility.

BioPlexus Corporation
3753 Howard Hughes Parkway - Suite 310
Las Vegas, NV 89109

Phone: 702-369-5971 FAX: 702-369-2607

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

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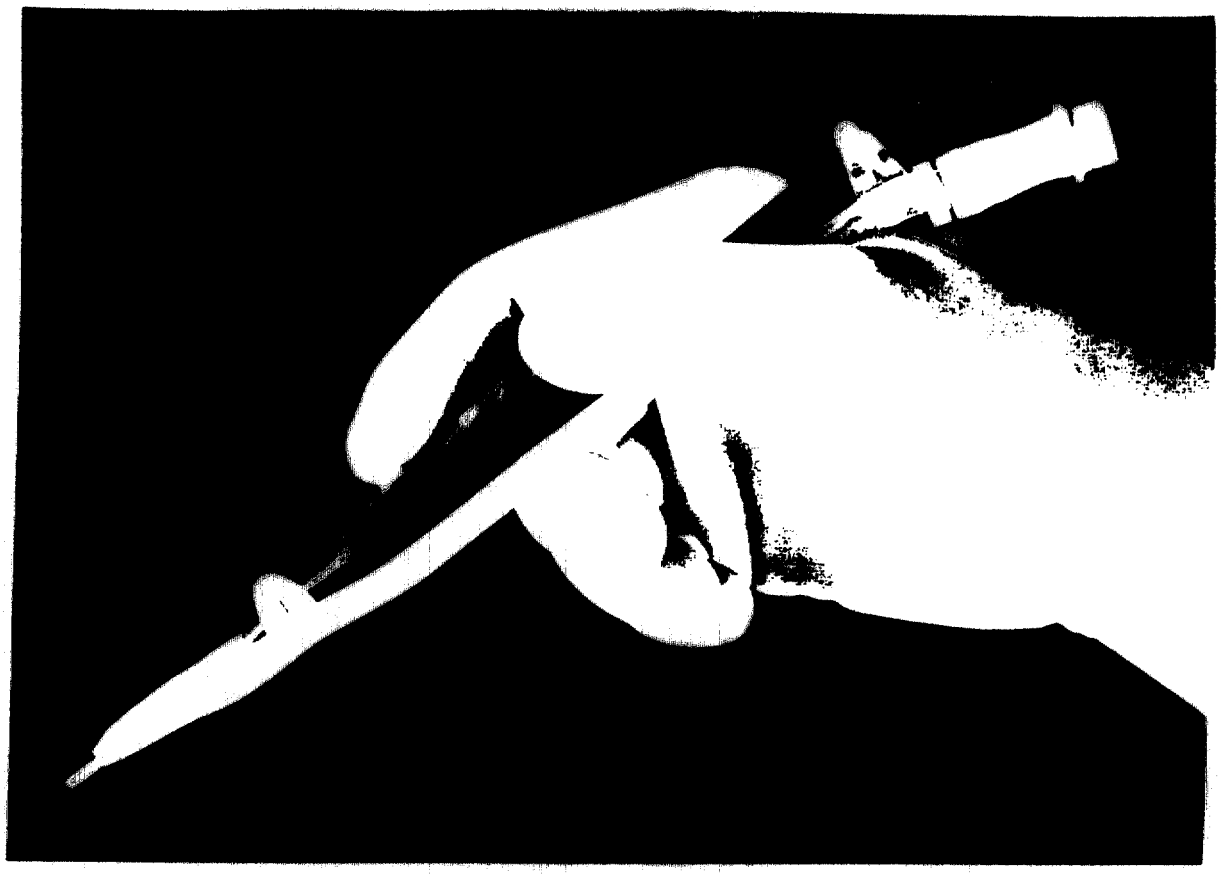

YOUR DANGER IS REAL

THE SOLUTION IS CLEAR

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

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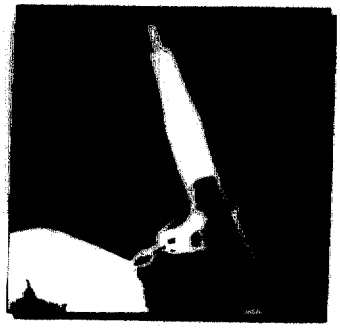
SECTION - E
E.c. - MARKETING MATERIALS
Implantech™ Associates, Inc. - SE-100

After determining the desired SE-100 length, simply trim the excess.



Then insert the knife into the SE-100 tip, and secure the two beadstraps.

Universally adaptable to all electrosurgical knives, the disposable SE-100 tip is easy to attach, clear for improved visibility, and can be cut to the optimum length for each procedure.

Additionally, it readily connects to any standard vacuum source, and occasional clogs are quickly dislodged by dipping the tip in sterile saline and pinching the blockage.

You do your best to ensure the patient's safety – now do the same for yourself. Order the SE-100 smoke aspiration tip from Implantech...and breathe easier in your next surgery.

U.S. Patent No. 5,224,944

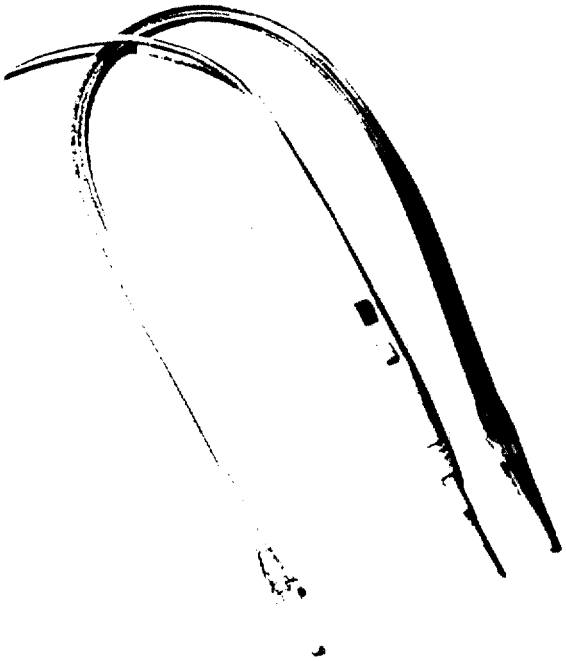
PLEASE NOTE
Each SE-100 smoke aspiration tip is sterile-packaged and disposable. Order in quantities of 25 units per box.

Implantech™
ASSOCIATES, INC.
2064 Eastman Avenue, Unit 101 • Ventura, CA 93003
800/733-0833 • 805/339-9415 • 805/339-9414 FAX

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

Records Processed under FOIA Request # 2015-7673; Released by CDRH on 10-8-2015

SECTION-E
E.c. - MARKETING MATERIALS
BioPlexus Corp. - Aspiration Tip



ODOROUS VAPOR AND PARTICLE REMOVAL

The **Aspiration Tip** is a vacuum-powered suction device for removing smoke and body fluids during surgical procedures. Commonly used in operations which require cutting or cauterizing tissue with an electrocautery instrument, the **Aspiration Tip** attaches directly to the electrocautery instrument.

BIOPLEXUS CORPORATION
3753 Howard Hughes Parkway
Suite 310
Las Vegas, Nevada 89109
(702) 369-5971
Fax (702) 369-2607

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

Records Processed under FOIA Request # 2015-7673; Released by CDRH on 10-8-2015

ASPIRATION TIP

Catalog Number AS-40001

The **Aspiration Tip** is a vacuum-powered suction device for removing smoke and body fluids during surgical procedures. Commonly used in operations which require cutting or cauterizing tissue, the **Aspiration Tip** attaches directly to the electrocautery instrument.

Features:

- **Low Cost**
- **Patented Design**
- **Single Pack** - ten per box
- **Low Profile** - for functional and aesthetic appeal
- **Translucent** - for visual identification of particle and bodily fluid transfer
- **Flexible** - for ease of attachment to electrocautery pen and to alleviate clogging
- **Heat Resistant** - withstands temperature of the electrocautery pen without degradation
- **Sterility** - supplied sterile for convenient use

Benefits and Advantages:

- Removes Smoke Plumes - reduces undesirable smoke and odor.
- Improves Vision - to the operative field and surgical facility.
- Removes Debris - eliminates small particles from the operative field.
- Removes Fluids - eliminates excessive fluids from the operative field.
- Easy to Assemble - tip fits coaxially over standard electrocautery pen.
- Cost Effective - does not require the purchase of additional equipment.
- Convenient to Use - easy attachment to pen, quick connect and disconnect to most wall suction and vacuum systems, tip can be trimmed to accommodate most blades.
- Comfortable - fits comfortably in surgeon's hand without hindering agility.
- Versatile - fits a wide variety of electrocautery knives.
- Effective - coaxial orientation reduces obstruction by aspirator during surgical procedure.

BIOPLEXUS CORPORATION

BIOPLEXUS CORPORATION
3753 Howard Hughes Parkway
Suite 310
Las Vegas, Nevada 89109
(702) 369-5971
Fax (702) 369-2607

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

Records Processed under FOIA Request # 2015-7673; Released by CDRH on 10-8-2015

SECTION - F

PREMARKET NOTIFICATION TRUTHFUL AND ACCURATE STATEMENT

I certify, in my capacity as Leader, Quality Assurance & Regulatory Affairs of Applied Medical Technology, Inc., I believe, to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Thomas W. Parkinson - Quality Assurance / Regulatory Affairs

Signature: Thomas W Parkinson Date: May 10, 1997

510(k) number: Not yet issued

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

Records Processed under FOIA Request # 2015-7673; Released by CDRH on 10-8-2015

SECTION - G

SAFETY AND EFFECTIVENESS STATEMENT

I certify to the best of my knowledge at this point in time, that I have conducted a reasonable search of all information known to me or otherwise available to me about types and causes of safety and/or effectiveness problems that have been reported for the Cauterization Smoke Evacuator. I further certify that I am aware of the types of problems to which the Cauterization Smoke Evacuator is susceptible and that the following summary of the types and causes of safety and/or effectiveness problems about the Cauterization Smoke Evacuator is, to the best of my knowledge at this point in time, complete and accurate.

1. SAFETY:

This device is an add-on to an Electro-Cauterization System. With this device by its self, there is no safety precaution required. However, when using an electro-cauterization system the operator must be familiar with all operating instructions and aspects of the electro-cauterization system. Do not use an electro-cauterization system in the presence of flammable gases, fluids, and/or oxygen enriched environments.

2. EFFECTIVENESS:

The problems can be virtually eliminated by providing adequate training in the form of complete instructions enclosed in the labeling for the electro-cauterization system (not part of this device), to the professional health care worker (electro-cauterization systems are not manufactured or distributed by Applied Medical Technology, Inc.). The Cauterization Smoke Evacuator device should be checked frequently to ensure the device is properly placed and is functional.

Submitted By (Name): Thomas W. Parkinson

Signature: May 10, 1997

Title: Leader, Quality Assurance / Regulatory Affairs

Name of Company: Applied Medical Technology, Inc.

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

Records Processed under FOIA Request # 2015-7673; Released by CDRH on 10-8-2015

SECTION - H

510(k) SUMMARY/STATEMENT CERTIFICATION

Reference: [510(k) not yet issued]

CHECK ONLY ONE:

☐ 1. **510(k) Summary.** Attached is a summary of safety and effectiveness information upon which an equivalence determination could be based.

■ 2. **510(k) Statement.** I certify that, in my capacity as Leader, Quality Assurance / Regulatory Affairs, of Applied Medical Technology, Inc., I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantiality equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

Thomas W. Parkinson

May 10, 1997

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

Records Processed under FOIA Request # 2015-7673; Released by CDRH on 10-8-2015

SECTION - I

I.1. - DRAFT PACKAGE LABELS

This label is located on each packaged bag.
(XXX's refer to unique numbers that will be assigned at a later date)

REF No.: X-XXXX
LOT XXXXXXXX
USE BEFORE: XX/XX XXXX-XX

CAUTERIZATION SMOKE EVACUATOR

CONTENTS:
STERILE EO
1 ea. Cauterization Smoke Evacuator

Manufactured By:
APPLIED MEDICAL TECHNOLOGY, INC.
Cleveland, OH USA
TEL: 216/475-5577 FAX: 216/475-5575

Sterile unless package is damaged or opened.
[redacted]
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

C-XXXX-00

READ DIRECTIONS FOR USE BEFORE USING THIS PRODUCT.

MADE IN U.S.A.

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

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SECTION - I

This label is located on each Box.
A Box contains 10 individually packaged devices

REF No.: X-XXXX
LOT XXXXXXXX
USE BEFORE: XX/XX XXXX-XX

CAUTERIZATION SMOKE EVACUATOR

CONTENTS:

STERILE EO
10 ea. Cauterization Smoke Evacuator

Manufactured by
APPLIED MEDICAL TECHNOLOGY, INC.
Cleveland, OH USA
TEL. 216/475-5577
FAX. 216/475-5575

SINGLE USE ONLY
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

READ DIRECTIONS FOR USE BEFORE USING THIS PRODUCT.

REF No.: X-XXXX
LOT XXXXXXXX
USE BEFORE: XX/XX XXXX-XX

CAUTERIZATION SMOKE EVACUATOR

X-XXXX-XX

MADE IN U.S.A.

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

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SECTION - I

I.2. - DRAFT DIRECTIONS FOR USE

Applied Medical Technology, Inc.
Cauterization Smoke Evacuator

INDICATIONS FOR USE:

The Cauterization Smoke Evacuator is an accessory device used to provide an air suction path for the reduction of gasses, body fluids, and smoke associated with the use of an electric cauterization system (such as a Bovie system). The Cauterization Smoke Evacuator is meant to be an accessory add-on device to most currently designed, marketed, and distributed electro-cauterization systems, and standard operating room suction systems (these systems are not manufactured or distributed by Applied Medical Technology, Inc.).

CONTRAINDICATION FOR USE:

Although the device itself presents no contraindications, an electro-cauterization system should not be used in the presence of flammable gases, objects, and/or oxygen enriched environments. The professional health care user of this device must be completely familiar with the operating parameters and usage of the electro-cauterization system being used in conjunction with this accessory device.

DIRECTIONS FOR USE:

The Cauterization Smoke Evacuator device is designed for placement over the end of the electro-cauterization pencil. **The tip of the cauterization pencil should extend 0.25mm (0.010") to 1.65mm (0.065") outside the Cauterization Smoke Evacuator.** Use of a band over the handle is made available to further secure the Cauterization Smoke Evacuator device tubing if required. **A Steri-Strip (tape supplied by user) may be used instead of the band.**

(Revisions above shown in **bold** - June 24, 1997)

Connect the christmas tree adapter to the operating room suction system.

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Use the electro-cautery unit as per manufacturers instructions.

CAUTION: When the smoke evacuating system is not in use, place the device away from the patient and any flammable objects, gasses, and/or fluids because of the possibility of accidental electro-cauterization activation.

SECTION - I

I.2. - DRAFT DIRECTIONS FOR USE - Continued

WARNING: DO NOT USE AN ELECTRO-CAUTERIZATION SYSTEM IN THE PRESENCE OF FLAMMABLE GASES, OBJECTS, AND/OR OXYGEN ENRICHED ENVIRONMENTS.

PROCEDURE:

1. Remove the Cauterization Smoke Evacuator device from the package and inspect for any visible defects. If defects are observed, do not use device. Obtain another package.

2. Slip the Cauterization Smoke Evacuator over the tip of the electro-cauterization system pencil. **The tip of the cauterization pencil should extend 0.25mm (0.010") to 1.65mm (0.065") outside the Cauterization Smoke Evacuator.** A band is provided to aid in securing the Cauterization Smoke Evacuator to the electro-cauterization system pencil, if required. **A Steri-Strip (tape supplied by user) may be used instead of the band.**

(Revisions above shown in **bold** - June 24, 1997)

3. Connect the other end of the Cauterization Smoke Evacuator to the operating room suction system. A christmas tree adapter is part of the Cauterization Smoke Evacuator and should adapt to most standard operating room suction systems.

4. Verify the standard operating room suction system is turned on and is operational.

5. The Cauterization Smoke Evacuator device will provide an air suction path for the reduction of gasses, body fluids, and smoke associated with the use of most electro-cauterization systems.

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SECTION - I

I.3. - DRAFT PROMOTIONAL MATERIAL

At this point in time, there is no draft promotional literature from Applied Medical Technology, Inc.

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

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SECTION - I

I.4. - INTENDED USE STATEMENT

The intended use of the Cauterization Smoke Evacuator is to provide an air suction path for the reduction of gasses, body fluids, and smoke associated with the use of an electro-cauterization type system. The Cauterization Smoke Evacuator is meant to be an accessory add-on device to most currently designed and distributed electro-cauterization systems (electro-cauterization systems are not manufactured or supplied by Applied Medical Technology, Inc.). Additionally the Cauterization Smoke Evacuator connects to most standard operating room type suction systems with the use of a universal christmas tree style adapter (surgical suction systems are not manufactured or supplied by Applied Medical Technology, Inc.).

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

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SECTION - I

I.5. - INDICATIONS FOR USE STATEMENT

The Cauterization Smoke Evacuator is an accessory device used to provide an air suction path for the reduction of gasses, body fluids, and smoke associated with the use of most electro-cauterization systems. The Cauterization Smoke Evacuator is meant to be an accessory add-on device to currently designed and distributed electro-cauterization systems, and most standard operating room suction systems.

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

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SECTION - J

DEVICE DESCRIPTION

The Applied Medical Technology, Inc. - Cauterization Smoke Evacuator is a device made of four (4) components.

The components consist of:

1. A specially shaped tip to fit over an electro-cauterization system pencil.
2. A section of tubing connected to the tip and an adapter.
3. An adapter to attach the tubing to most suction systems.
4. A band is supplied to aid in attaching the device to an electro-cauterization system pencil, if required.

See the drawing on page J.2.

The device is designed for use with most electro-cauterization systems (not manufactured or distributed by Applied Medical Technology, Inc.).

The device is sold packaged as sterile, single use, and disposable.

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

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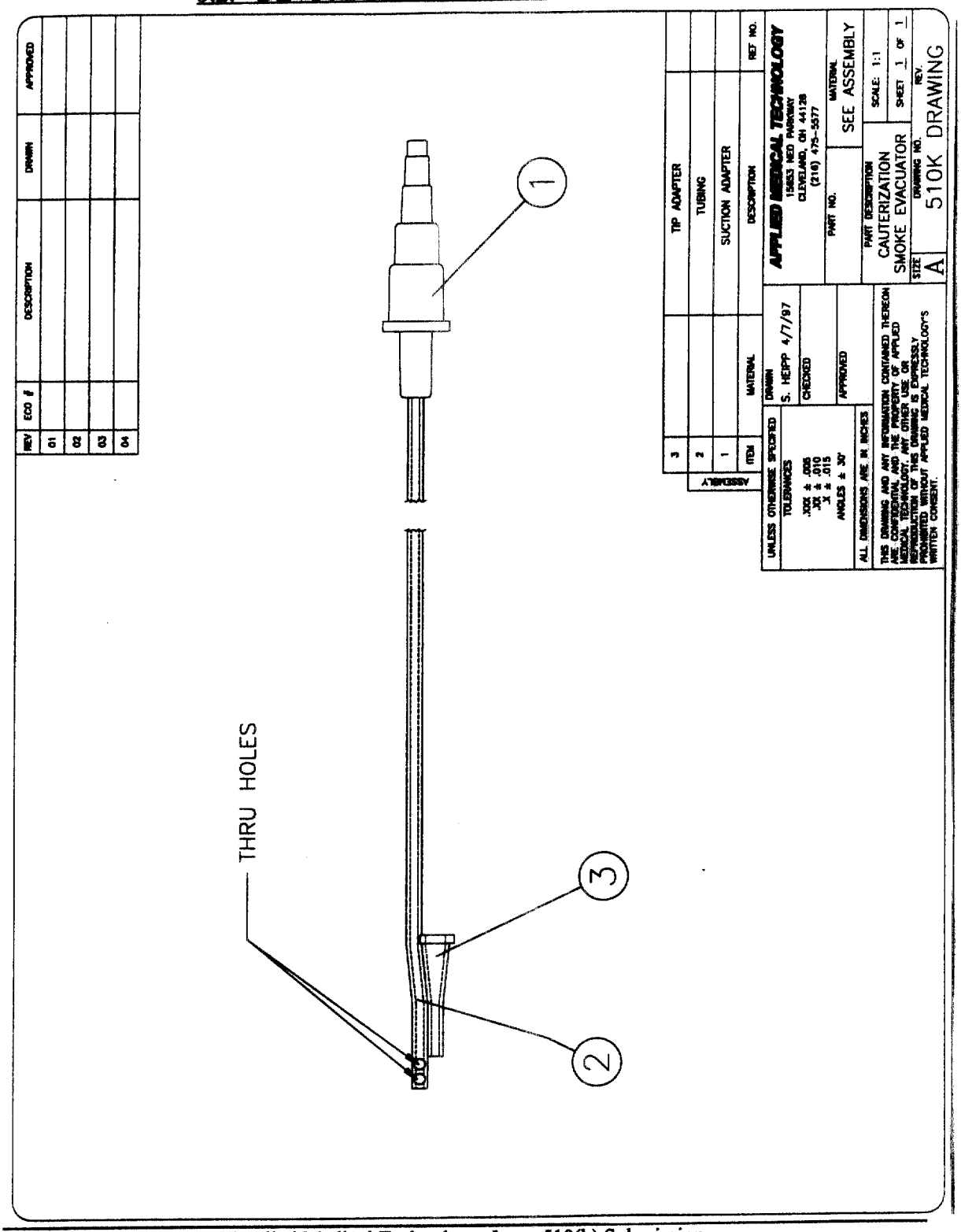
CONFIDENTIAL

SECTION - J

J.2. - DEVICE DRAWING - *CONFIDENTIAL -*



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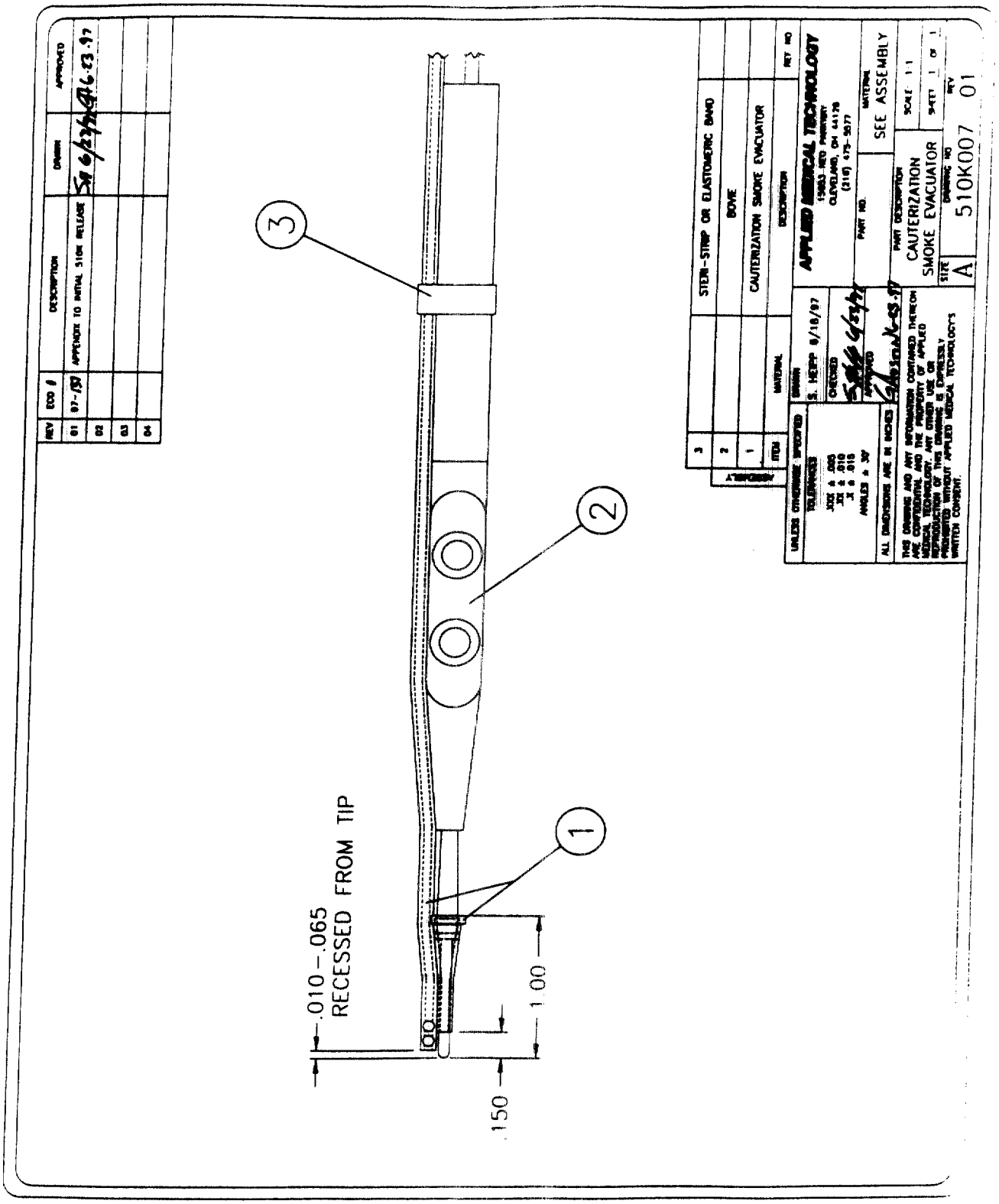

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION - K

K.1. - LIST OF MATERIALS USED

Tubing is purchased:

Polyurethane Tubing. Source of tubing may be from:

(b) (4)

[redacted]

Adapter is purchased: Qosina Enteral Adapter part number 41410.

Qosina Corporation
150-Q Executive Drive
Edgwood, NY 11717-8329

(b) (4)

[redacted]

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

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SECTION - K

K.2. - BIOCOMPATIBILITY INFORMATION DATA

The components used for this device were purposely chosen from those that have sufficient data and information in regards to biocompatibility requirements and concerns.

The following highlights the various companies supplying components. Reference detailed data which is included as an addendum to this 510(k) request.

Polyurethane Tubing - Source of tubing may be from:

(b) (4) [redacted]

Adapter is purchased: Qosina Enteral Adapter part number 41410.

Qosina Corporation
150-Q Executive Drive
Edgwood, NY 11717-8329

Adhesive is purchased: (b) (4) [redacted]

(b) (4) [redacted]

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

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SECTION - L

PERFORMANCE DATA TO DETERMINE EQUIVALENCE

Performance data of the device was determined not to be required since enough existing information is available and included.

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

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SECTION - M

STERILIZATION INFORMATION

M.a. Sterilization Method:	Ethylene Oxide (EtO) [100% EtO]
Sterilization Contractor:	Medical Manufacturing Corp. (M.M.C.) 2205 East 33rd Street Erie, PA 16510-2555
Testing Lab:	Ethox Corp. 251 Seneca Street Buffalo, NY 14204-2088
M.b. Sterility Assurance Level:	10^{-6}
M.c. Cycle Validation:	½ cycle and full cycle. Overkill. Method of Validation: Overkill approach as described in the Association for the Advancement of Medical Instrumentation (AAMI) recommended guidelines (3188).
M.d. Residual Levels:	Determined by an H_2O extraction at 37° for simulated use. Ethylene Oxide (EtO): 22 ppm Ethylene Chlorohydrin (EtCh): <12T ppm* Ethylene Glycol (EtG): 40 ppm *T = Trace Peak Detected
M.e. Packaging:	Mylar Pouch with Tyvek Cover. Expiration Date: Three (3) years from date of sterilization.
M.f. Pyrogenic Level:	No pyrogen level claims are made.

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SECTION - N

SOFTWARE VALIDATION

I certify that there are no Software components related in any way to this device. Therefore, this section for Software Validation is not applicable to this device.

Thomas W. Parkinson
Quality Assurance / Regulatory Affairs

Date: May 10, 1997

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

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SECTION - O

O.1. - KIT CONTENTS

Each Device comes with Directions for Use.
The devices are packaged 10 per Box.

1 each - Cauterization Smoke Evacuator device

1 each - Directions For Use

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

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SECTION - O

O.2. - KIT CERTIFICATION

I certify that the components of the Applied Medical Technology, Inc. - Cauterization Smoke Evacuator are either:

(1) legally marketed pre-amendment devices,

(2) exempt from premarket notification (consistent with the exemption criteria described in the classification regulations and the limitations of exemptions from Section 510(k) of the Act (example: 862.9), or

(3) have been found to be substantially equivalent through premarket notification process for the use(s) for which the kit is to be intended. (I am not claiming or causing a new use for the components.)

I further certify that these components are not purchased in 'bulk', but are purchased in finished form, i.e., they are packaged, labeled, etc., consistent with their pre-amendments, exemptions, or premarket notification criteria and status.

Thomas W. Parkinson
Quality Assurance / Regulatory Affairs

May 10, 1997

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