AUG 6 1998

bissinger

2. 510(k) Summary of Safety and Effectiveness
Günter Bissinger Medizintechnik GmbH

As required by Section 807.92(c)

Submitted by:

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The Netherlands

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Date Summary Prepared:

May 26, 1998

Name of the Device:

Proprietary Name:	Bissinger Cables
Common/Usual Name:	Bipolar Cable/Cord
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories (per 21 CFR 878.4400)

Description:

Bissinger cables are a line of non-sterile, reusable bipolar foot activated cables fitting Erbe, Martin, Valleylab, Aesculap GK50, Codman CMC II, and other ES units.

Intended Use:

The Bissinger bipolar cable/cord is intended for use in electrosurgical procedures to provide transmission of electrical power from the bipolar output of an electrosurgical generator to a bipolar foot-activated instrument.

This device is intended for use by qualified medical personnel trained in the use of electrosurgery.

Industry Standards:

Bissinger certifies to comply with the required IEC, ANSI, and AAMI standards for manufacture, cleaning, sterilization and for the validation of these processes.

g) Predicate Devices:

Olsen Electrosurgical Inc. Bipolar Cables
Valleylab Reusable Cords/Connectors

h) Predicate Comparison:

A table comparing the Bissinger Bipolar Cables to predicate devices is attached.

Bissinger Bipolar Cables Substantial Equivalence Comparison to Predicate Devices:

Manufacturer	**Bissinger**	**Olsen**	**Valleylab**
Device	Bipolar cable	Bipolar cable	Bipolar cable
Model(s)	80100xx	870,871,872	E0019
Intended Use	Transmission of electrical power from an electrosurgical generator to a bipolar foot activated instrument	Transmission of electrical power from an electrosurgical generator to a bipolar foot activated instrument	Transmission of electrical power from an electrosurgical generator to a bipolar foot activated instrument
Length of Cable	3 meters, 5 meters	10 foot (3.05m)	12 foot (3.66m)
Material of Outer Cable Insulation	Silicone	Silicone	Silicone
Reusable/Single Use?	Reusable	Reusable	Reusable
Provided Sterile?	No	No	No
Connector Types Instrument End	Two types: either for instruments with standard American two-pin type plugs, or for instruments with the standard European flat plug	Two types: either for instruments with standard American two-pin type plugs, or for instruments with the standard European flat plug	For instruments with standard American two-pin type plugs
Connector Types Generator End	Martin, Erbe, Valleylab, Aesculap GK50, Codman CMC II, standard type fitting all generators utilizing the standard receivers for "Banana" inserts	Martin (872), Eder (872), Wolf (872), standard type fitting all generators utilizing the standard receivers for "Banana" inserts (870,871)	Valleylab

Anschrift: Geschäftsführer: Günter Bissinger, Volksbank Emmendingen (BLZ 680 920 00) 8 7029 18

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 6 1998

Ms. Dagmar S. Maser
'Günter Bissinger Medizintechnik GmbH
FDA Liaison
Business Support, International
Amstel 320-I
1017 AP Amsterdam - The Netherlands

Re: K981919
Trade Name: Bissinger Cables, Catalog Number 801000XX
Regulatory Class: II
Product Code: GEI
Dated: May 27, 1998
Received: June 1, 1998

Dear Ms. Maser:

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 requirement, 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.

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,

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

Günter Bissinger Medizintechnik GmbH

510(k) Number: K981919

Device Name: Bipolar Cable/Cord

Classification Name: Electrosurgical Cutting and Coagulation Device & Accessories

Product Code: 79 GEI Class II 21 CFR 878.4400

INDICATIONS FOR USE:

The Bissinger bipolar cable/cord is intended for use in electrosurgical procedures to provide transmission of electrical power from the bipolar output of an electrosurgical generator to a bipolar foot-activated instrument.

This device is intended for use by qualified medical personnel trained in the use of electrosurgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981919

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

V

(Optional Format 1-2-96)