K970968

Summary of Safety and Effectiveness Information Premarket Notification, Section 510(k)	**bissinger®** **detachable bipolar coagulation-forceps** Medizintechnik, GmbH

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. **Device Name:**

Trade Name:	**bissinger® detachable bipolar coagulation-forceps**
Common Name:	Coagulation forceps
Classification Name:	Bipolar, Coagulator-Cutter, Endoscopic, Bipolar and Accessories

2. **Establishment Name & Registration Number:**

Name: Medizintechnik, GmbH
Number: Pending

3. **Classification:**

§ 884.4150 Bipolar endoscopic coagulator-cutter and accessories.

(a) Identification. A bipolar endoscopic coagulator-cutter is a device used to perform female sterilization and other operative procedures under endoscopic observation. It destroys tissue with high temperatures by directing a high frequency electrical current through tissue between two electrical contacts of a probe. This generic type of device may include the following accessories: an electrical generator, probes, and electrical cables. **(b)** Classification. Class III (premarket approval). **(c)** Date PMA or notice of completion of a PDP is required. No effective date has been established of the requirement for premarket approval. See § 884.3.

[45 FR 12684-12720, Feb. 26, 1980, as amended at 52 FR 17741, May 11, 1987]

Device Class:	Class III
Classification Panel:	OB/GYN
Product Code:	85HIN

4. **Device Description:**

Cat. #	Description
xx123	Forceps Body
xx789	Exterior tube (3 lengths)
xx234	Interior tube (3 lengths)
xx567	1mm Electrode (fluted bit) (3 lengths)
xx890	3mm Electrode (tong-type bit) (3 lengths)
xx345	Hirsch-electrode (rippled bar) (3 lengths)
xx678	Erbe-type plug
xx901	Martin/Berchtold-type plug
xx012	Codman-type plug
xx111	Valleylab-type plug
xx222	Cable

1 of 2

Forceps Body (grip). The handle is the attachment point for the other elements of the coagulation forcep. The exterior tube, internal tube, electrode and the current cable (with or without addapter) attach here.

Exterior tube. Available in three working lengths, 200mm, 340mm and 450mm. Please refer to the graphic representations in Appendix II for additional information.

Interior tube (sliding tube). Available in three working lengths, 200mm, 340mm and 450mm. Please refer to the graphic representations in Appendix II for additional information.

1mm Electrode (fluted bit). Available in three working lengths, 200mm, 340mm and 450mm to match the interior and exterior tube length selected. Please refer to the graphic representations in Appendix II for additional information.

3mm Electrode (tong-type bit). Available in three working lengths, 200mm, 340mm and 450mm to match the interior and exterior tube length selected. Please refer to the graphic representations in Appendix II for additional information.

Hirsch-electrode (rippled bar). Available in three working lengths, 200mm, 340mm and 450mm to match the interior and exterior tube length selected. Please refer to the graphic representations in Appendix II for additional information.

Erbe-type plug. Used to connect the **bissinger® detachable bipolar coagulation-forceps** to an Erbe brand current generator. Please refer to the graphic representations in Appendix II for additional information.

Martin/Berchtold-type plug. Used to connect the **bissinger® detachable bipolar coagulation-forceps** to an Martin/Berchtold brand current generator Please refer to the graphic representations in Appendix II for additional information.

Codman-type plug. Used to connect the **bissinger® detachable bipolar coagulation-forceps** to a Codman brand current generator. Please refer to the graphic representations in Appendix II for additional information.

Valleylab-type plug. Used to connect the **bissinger® detachable bipolar coagulation-forceps** to a Valleylab brand current generator. Please refer to the graphic representations in Appendix II for additional information.

Cable. Provides the flexible insulated cable to connect the instrument to the current generator.

5. Cleaning/Sterilization/Re-sterilization:

The surgical instruments required to properly use the device are supplied clean only and must be sterilized prior to each use. Remove all shipping and packaging materials before sterilization. Wash all instruments thoroughly prior to sterilization. For the instruments, the recommended method is steam autoclave sterilization. The recommended sterilization cycle is based on AAMI guidelines. The cycle is saturated steam at 270° F for 15 minutes.

6. Equivalence:

Based on the materials, intended uses, design and clinical technique, the **bissinger® detachable bipolar coagulation-forceps** are substantially equivalent to the referenced legally marketed WISAP *bipolar coagulators available from* WISAP USA.

7. Feature Comparison Table:

FEATURE	bissinger®	WISAP - USA	SE?
Intended Use:			Yes
Materials:	PEEK, PTFE, stainless steel, Silicone, Pa	Polyethylene, stainless steel,	Yes
Length:	200mm, 340mm & 450mm	330mm & 450mm	Yes
Forcep Style:	1mm Electrode (fluted bit) 3mm Electrode (tong-type bit) Hirsch-electrode (rippled bar)	WISAP - #7585, 7585-1 WISAP - #7585, 7585-1 WISAP - #7585-4, 7585-5	Yes Yes Yes
Insulation Material:	PTFE	PTFE	Yes
UL Compliant:	UL-544	UL-544	Yes
ISO Compliant:	ISO-9001	ISO-9001	Yes
Manufacturer:	Medizintechnik, GmbH	WISAP USA	Yes
K-Number	Pending	Unknown	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 1998

Mr. David W. Schlerf
Medizintechnik, GMBH
c/o Buckman Company, Inc.
1000 Burnett Avenue, Suite 450
Concord, CA 94520

Re: K970968
Bissinger® Detachable Bipolar Forceps
Dated: August 20,.1997
Received: February 20, 1998
Regulatory Class: II
21 CFR 884.1720/Procode: 85 HET
21 CFR 876.4300/Procode: 78 KNS

Dear Mr. Schlerf:

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

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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K970968

Device Name: Ussinger® detachable bipolar coagulation-forceps

Indications For Use:

Bipolar tissue coagulation in:
Gynecology and
Laparascopic surgical procedures

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K970968

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional format 1-2-96)