OCT 2 7 2004

1. Device Name

Trade Name: BiTech Bipolar Scissors
Common Name: Bipolar Scissors

2. Classification

Device:	Device, Electrosurgical, Cutting & Coagulation & Accessories
Device description:	Electrosurgical cutting and coagulation device and accessories.
Medical Specialty:	Part 878, General & Plastic Surgery
Product Code:	GEI
Regulation Number:	878.4400
Device Class:	2

3. Substantial Equivalence

BiTech Bipolar Scissors are substantially equivalent to other legally marketed Bipolar Scissors from different manufacturers, e.g.

- Ethicon, Inc. (K981361);
- Enable, (K972558).

4. Description of the Device

BiTech bipolar scissors enable cutting and dissection with simulataneous bipolar coagulation. They can also be used for precise pinpoint or zone coagulation of blood-vessels and tissue. The various working lengths allow the scissors to be used for a large number of applications in open surgery.

A petented construction priciple, which was developed by Dr. J. Manushakian*, ensures that the scissors are both easy to use and to repair. The electrical contacts for both scissor blades are conducted via one section of the handle, i. e. the connection cable only needs to be attached to one ring, which significantly reduces reference duriong handling. The scissor blades are flexibly joined by means of a standard steel scissor screw which does not need to be insulated and, as a result, is not subject to wear.

***Patented: US 6,355,035, EPO 99107816.3.**

5. Intended Use

BiTech bipolar scissors are designed for dissecting, cutting and bipolar coagulation of tissue during general surgical procedures.

The BiTech Bipolar Scissors has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

6. Performance Standards

DIN EN 60601-1: Medical electrical equipment - Part 1: General requirements for safety (IEC 60601-1:1988 + A1:1991 + A2:1995); German version EN 60601-1:1990 + A1:1993 + A2:1995; Version: 01-Mar-1996;

DIN EN 60601-2-2: Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment (IEC 60601-2-2:1998); German version EN 60601-2-2:2000; Version: 01-Aug-2001;

ANSI/AAMI HF18-2001: Electrosurgical Devices; Version: 01-May-2001.

7. Sterilization by User

BiTech Bipolar Scissors are delivered in non-sterile conditions. The user may sterilize these devices by using a validated and applicable sterilization process.

Cleaning and Maintenance

Every surgical instrument should be disinfected and thoroughly cleaned after each use. Proper cleaning, inspection and maintenance will help ensure correct function of the surgical instrument. Clean, inspect and test each instrument carefully. Sterilise all instruments before surgery. A good cleaning and maintenance procedure will extend the useful life of the instrument.

Special attention must be paid to slots, stops, ends, hollow tubes and other highly inaccessible areas. Check insulation, cables and connectors for cuts, voids, cracks, tears, abrasions, etc.

Do not use damaged instruments.

Cleaning and rinsing must take place immediately after each use for best effect. Failure to clean promptly may result in adherent particles or dried secretions that may resist cleaning and complicate or resist future sterilisation.

Instruments must be completely cleaned and rinsed of all foreign matter.

Use warm water and a commercially available instrument pre-soak or cleaning agent. Enzymatic cleaners (such as Enzol™) must be used to remove protein deposits. Follow the enzymatic cleaner's instructions; rinse thoroughly.

- Do not use corrosive cleaning agents (i.e. bleach). Cleaning solutions and rinses at or near a neutral pH (7.0) are best.
- Do not use abrasive cleaners.
- Only a soft bristle brush should be used.
- Immerse the entire device in detergent and clean while soaking.
  Rinse with sterile deionized water.
  Can be disinfected in the washing machine up to 203°F (95°C).
- Rinse thoroughly with distilled water.
- Prepare for storage and/or sterilisation.

Sterilisation

Only a validated steam-sterilization process according DIN EN 554 that uses a sterilization cycle of 137°C / 280°F, 3 bar, for min. 15 minutes has to be used.

(Note: Contact the manufacturer of your steam autoclave to confirm appropriate temperatures and sterilisation times.)

Caution: Autoclave temperatures should not exceed 280°F (137°C); handles, insulation or other non-metallic parts may be damaged

Do not sterilise with hot air.

Do not use 'Flash' autoclave procedures.

8. Conclusion

Based on the available 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that Bissinger BiTech Bipolar Scissors are substantially equivalent to the existing legally marketed devices under Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 2004

Guenter Bissinger Medizintechnik GmbH
c/o Mr. Franz Menean
Managing Director
MEDAGENT GmbH & Co. KG
47, Griesweg
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Germany 78570

Re: K042077
Trade/Device Name: BiTech Bipolar Scissors
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: July 26, 2004
Received: August 11, 2004

Dear Mr. Menean:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

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

Enclosure

Indications for Use

510(k) Number (if known): **K042077**

Device Name: **BiTech Bipolar Scissors**

Indications for Use:

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The BiTech Bipolar Scissors has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

Prescription Use __**YES**___ AND/OR Over-The-Counter Use __**NO**__
(Part 21 CFR 801 Subpart D) (21 SFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K042077