JUN 14 2006

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

K052759

Date: September 28, 2005

Submitter:

Name:	Dannoritzer Medizintechnik GmbH & Co. KG
Address:	Brenntenstr. 14 Tuttlingen, Germany 78532
Contact Person:	Axel Dannoritzer General Manager
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Product:

Trade Name:	DAN Monopolar Lap Accessories
Classification:	Class II
Common Name:	Laparoscope Accessories for General & Plastic Surgery
Classification Name:	Laparoscope, General & Plastic Surgery (GCJ, 21 CFR 876.1500) Electrosurgical Cutting & Coagulation & Accessories (GEI, 21 CFR 878.4400)

Predicate Devices:

- Miltex Laparoscopic Instruments, Miltex, Inc., K043013
- Laparoscopic Electrode, Megadyne Medical Products, K040699

Device Description: **DAN Monopolar Lap Accessories** consist of

- Standard insulated monopolar handles
- Insulated shafts
- Class I inserts (forceps, scissors, biopsy cups, needle holders)
- Electrodes

The device is reusable and provided non-sterile. It must be cleaned and sterilized before use.

Intended Use: **DAN Monopolar Lap Accessories** are reusable devices (forceps and electrodes) intended to be used in general laparoscopic surgical procedures requiring the use of electrosurgical cutting and/or coagulation.

Performance Data: Design analysis and comparison confirm that basic functional characteristics are substantially equivalent to the predicate devices cited and raise no new issues of safety and effectiveness.

Conclusion: Based upon the product technical information provided, intended use and performance information provided in this premarket notification, **DAN Monopolar Lap Accessories** have been shown to be substantially equivalent to the current legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 14 2006

Dannoritzer Medizintechnik GmbH
& Co. KG
% Business Support International
Ms. Angelika Scherp
Amstel 320-I
Amsterdam 1017AP

Re: K052759
Trade/Device Name: DAN Monopolar Lap Accessories
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: May 15, 2006
Received: May 18, 2006

Dear Ms. Scherp:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

INDICATIONS FOR USE

510(k) Number (if known): K052759

Device Name: DAN Monopolar Lap Accessories

Indications for Use:
DAN Monopolar Lap Accessories are reusable devices (forceps and electrodes) intended to be used in general laparoscopic surgical procedures requiring the use of electrosurgical cutting and/or coagulation.

Prescription Use _X_ AND/OR **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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, and Neurological Devices

510(k) Number K052759