K024811

JUN 19 2002

mtp technical medical promotion

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of MTP's knowledge.

Application:

MTP Medical Technical Promotion GmbH
P.O. Box 4529
d-78510, Tuttlingen
telephone: +49/7461/96630-25
(310) 558-1500

Contact:

James A. Lee, Ph.D.
(310) 410-2769

Device Identification:

Common Name:
Disposable Tubing Set

Trade Name: (optional)
Unidrive® II Plus Disposable Tubing Set

Indication: The MTP Unidrive® II Plus Disposable Tubing Set is intended to be utilized with the Karl Storz Unidrive® II Plus System for the controlled infusion of sterile irrigant solution during ENT endoscopic surgical surgery.

Device Description: The MTP Unidrive® II Plus Disposable Tubing Set is utilized with the Karl Storz Unidrive® II Plus System. It is sold as sterile and single use device.

Substantial Equivalence: The MTP Unidrive® II Plus Disposable Tubing Set is substantially equivalent to the predicate device since the basic features and intended uses are identical.

Signed: _____
James A. Lee, Ph.D.

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SUBSTANTIAL EQUIVALENCE TABLE FOR MTP Unidrive® II Plus DISPOSABLE TUBING SET

Manufacturer	MTP	KSEA(K003994)
Components	Irrigation tubing, roller pump tubing, tubing connectors, and a irrigation bag piercing spike	Same
Irrigation tubing lengths	Input: 150 cm Output: 310 cm	Same
Tubing, connector, and spike materials	Medical grade elastomer and plastics	Same
Sterile, Single Use	Yes	Same
Sterilization Method	Ethylene Oxide	Same
Packaging	Peel pouches	Same
Intended Use	For use with the Karl Storz Unidrive® II Plus System for the controlled infusion of sterile irrigant solution during ENT endoscopic surgical surgery	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2002

Medical Technical Promotion GmbH
c/o James Lee, Ph.D.
600 Corporate Pointe
Culver City, CA 90230

Re: K021811
Trade/Device Name: MTP Unidrive® II Plus Disposable Tubing Set
Regulation Number: 21 CFR 874.4250
Regulation Name: ENT Electric or Pneumatic Surgical Drill
Regulatory Class: Class II
Product Code: ERL
Dated: May 31, 2002
Received: June 3, 2002

Dear Mr. Lee:

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K021811

Device Name: MTP Unidrive® II Plus Disposable Tubing Set

Indication for Use: The MTP Unidrive® II Plus Disposable Tubing Set is intended to be utilized with the Karl Storz Unidrive® II Plus System for the controlled infusion of sterile irrigant solution during ENT endoscopic surgical surgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over-the-Counter Use: _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K021811