JUN 3

K990910

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.

Applicant:

mtp medical technical promotion gmbh
p.o. box 4529 • d-78510 tuttlingen
tel.: +49/7461/96630 - 0
fax: +49/7461/96630 - 25

Contact:

Kevin Kennan
(310) 410-2769

Device Identification:

Common Name:
Irrigation Tubing Sets

Trade Name: (optional)
MTP Hamou Endomat Disposable Tubing Sets

Indication: The MTP Hamou Endomat Disposable Tubing Sets are intended for use by qualified surgeons for the controlled infusion of sterile irrigant solution into body cavities during laparoscopic and hysteroscopic procedures.

Device Description: The MTP Hamou Endomat Disposable Tubing Sets are intended for use by qualified surgeons for the controlled infusion of sterile irrigant solution into body cavities during laparoscopic and hysteroscopic procedures. The body contact materials are PVC, silicone, polyolefin, and Makrolon.

Substantial Equivalence: The MTP Hamou Endomat Disposable Tubing Sets are substantially equivalent to the predicate device since the basic features, design and intended uses are the same.

Signed: _____

Kevin Kennan

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 6 1999

Mr. Kevin Kennan
Senior Regulatory Affairs Specialist
MTP Medical Technical Promotion GMBH
P.O. Box 4529
D-78510 tuttlingen

Re: K990910
MTP Hamou Endomat Disposable Tubing Sets
Dated: February 26, 1999
Received: March 18, 1999
Regulatory Class: II
21 CFR 884.1690/procode: 85 HIH
21 CFR 884.1720/Procode: 85 HET

Dear Mr. Kennan:

This letter corrects our substantially equivalent letter of June 3, 1999, regarding the address being incorrect. We apologize for the error and hope it has not caused any inconvenience.

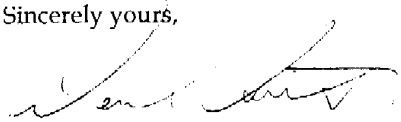
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 continue 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. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



CAPT Daniel Schultz, M.D.
Acting 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 (if known): K990910

Device Name: Hamou Endomat Disposable Tubing Set

Indications for Use: The MTP Hamou Endomat Disposable Tubing Set is intended to be utilized with the Karl Storz Hamou Endomat Irrigation System for the controlled infusion of sterile irrigant solution into body cavities during laparoscopic and hysteroscopic procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990910