

JAN 20 2000

**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  
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tel.: +49/7461/96630 - 0  
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**Contact:** Kevin Kennan  
(310) 410-2769

**Device Identification:** **Common Name:**  
Disposable Trocars

**Trade Name: (optional)**  
MTP Disposable Trocars

**Indication:** The MTP Disposable Trocars are manually operated surgical devices intended for abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments and endoscopes

**Device Description:** The MTP Disposable Trocars body contact material is polycarbonate.

**Substantial Equivalence:** The MTP Disposable Trocars are substantially equivalent to the predicate devices since the basic features, design and intended uses are the same.

Signed:

A handwritten signature in black ink, appearing to read 'Kevin Kennan', is written over a horizontal line.

Kevin Kennan



JAN 20 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MTP Medical Technical Promotion GmbH  
C/O Mr. Kevin Kennan  
P.O. Box 1954  
Culver City, California 90232

Re: K994066  
Trade Name: MTP Disposable Trocars  
Regulatory Class: II  
Product Code: GCJ  
Dated: November 30, 1999  
Received: December 1, 1999

Dear Mr. Kennan:

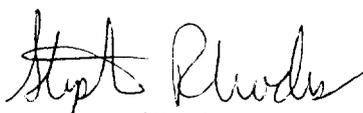
We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Devices 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 devices, 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 devices 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 devices 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 requirement, 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 devices 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

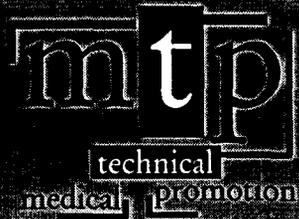
If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your devices, please contact 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/dsmamain.html>".

Sincerely yours,

*for* 

James E. Dillard III  
Acting Director  
Division of General and  
Restorative Devices  
Office of Devices Evaluation  
Center for Devices and  
Radiological Health

Enclosure



510(k) Number (if known): K994066

Device Name: MTP Disposable Trocars

Indications for Use: These instruments are manually operated surgical devices intended for abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments and endoscopes.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*[Handwritten Signature]*

(Division Sign-Off)  
Division of General Restorative Devices

510(k) Number K994066

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

(Optional Format 1-2-96)