K033591

JUN 3 - 2005

# 510(k) SUMMARY

**Submitter**: ClearMedical, Inc.
1776 136th Place NE
Bellevue, WA 98005

**Contact**: Gene Lim
Ph: 425-460-2779
Fax: 425-401-1515

**Date**: June 2, 2005

**Trade name**: ClearMedical Reprocessed Trocars

**Common name**: Bladed and Non-Bladed Trocars

**Classification name**: Endoscope and Accessories (Class II, 21 CFR 876-1500)

**Product Code**: NLM - Laparoscope, General & Plastic Surgery, Reprocessed

**Predicate Device(s):**

The trade names of current legally marketed predicate devices are:

- Ethicon Endopath® Dilating Tip Trocar (5mm-12mm)
- Ethicon Endopath® Tristar® Trocar (5mm-12mm)
- Ethicon Endopath® Tristar® Blunt Tip Trocar (10mm-12mm)

The 510(k) Premarket Notification numbers for these devices are:

- K020428 Endopath® Dilating Tip Trocar
- K011538 Endopath® Non-Bladed Solid Obturator (with sleeve)
- K011257 Endopath® Non-Bladed Obturator Trocar System (5mm)

**Device description**:

Reprocessed endoscopic trocars consist of an obturator and sleeve. The trocar sleeve has a stopcock valve for gas insufflation and a desufflation lever for gas evacuation. The trocar obturator are either flat bladed, pyramidal, or blunt tip. Bladed and dilating tip obturators have a safety shield that exposes the blade during insertion and retract over the tip after the operative cavity has been penetrated.

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**Intended use**:

Reprocessed trocars are used in thoracic, gynecologic, laparoscopy, and other abdominal procedures to establish a path of entry for endoscopic instruments.

**Technological characteristics**:

Reprocessed trocars are used devices that are cleaned, inspected, tested, packaged, and sterilized for an additional single patient use. The technological characteristics of design, material, and functional performance of reprocessed trocars are unchanged and remain equivalent to the predicate devices.

**Test data**:

Validation of cleaning, performance, and packaging, and sterilization, as well as biocompatibility testing, demonstrate that reprocessed trocars perform as intended and are safe and effective.

**Conclusion**:

Based on information provided in this submission, ClearMedical Reprocessed Trocars are substantially equivalent to the identified predicate devices and are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 - 2005

Mr. Gene Lim
Director of Product Development
ClearMedical Incorporated
1776 136th Place NE
Bellevue, Washington 98005

Re: K033591
Trade/Device Name: Reprocessed Trocars (see additional list)
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, nose, and throat manual surgical instrument
Regulatory Class: II
Product Code: KBG
Dated: April 4, 2005
Received: April 5, 2005

Dear Mr. Lim:

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/industry/support/index.html.

Sincerely yours,

Miriam C. Provost

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Listing of device being cleared in K033591:

| Ethicon model | ClearMedical Part Number |
|---|---|
| 355S | 10154-S-1 |
| 355T | 10154-S-2 |
| 355L | 10154-S-3 |
| 511S | 10154-S-4 |
| 512S | 10154-S-5 |
| 355SM | 10155-S-1 |
| 355SD | 10155-S-2 |
| 355TM | 10155-S-3 |
| 355LM | 10155-S-4 |
| 355LD | 10155-S-5 |
| 578SD | 10155-S-6 |
| 511SM | 10155-S-7 |
| 511SD | 10155-S-8 |
| 512SM | 10155-S-9 |
| 512SD | 10155-S-10 |
| 512B | 10157-S |

# Indications for Use

510(k) Number (if known): K033591

Device Name: Reprocessed Trocars

Indications for Use:

The ClearMedical Reprocessed Endopath® Tristar® Blunt Tip Surgical Trocar, ClearMedical Reprocessed Endopath® Tristar® Surgical Trocar, and ClearMedical Reprocessed Endopath® Dilating Tip Trocar have application in thoracic, gynecologic laparoscopy, and other abdominal procedures to establish a path of entry for minimally invasive instruments.

Contraindications:

These instruments are not intended for use when minimally invasive techniques are contraindicated.

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

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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



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