

APR -1 1998

February 13, 1998
Sabre BT™ Blunt-Tip Surgical Trocar

510(k) Summary

K980804

Pursuant to 512(i)(3)(A) of the Food, Drug and Cosmetic Act, Endoscopic Concepts Inc. is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that information will be made available upon request of any person." Apple Medical chooses to submit a summary of the safety and effectiveness information. The summary is as follows:

Device Trade Name: Sabre BT™ Blunt-Tip Surgical Trocar

Owner/Operator: Endoscopic Concepts Inc.
1191 North Federal Highway
Delray Beach, FL 33483
FDA Registration # 9011363

Manufacturing Site: Contract manufacturer selected and controlled by:
Endoscopic Concepts Inc.
2 Maple Street
P.O. Box 375
Mendon, MA 01756
FDA Registration # 1058828

Device Generic Name: Laparoscopic trocar/cannula

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II, Performance Standards (21 CFR 884.1720).

Predicate Devices:

Sabre Ultimate Shielded Trocars	TroGard™ Blunt Tip Trocar System
Manufactured and Distributed by:	Manufactured and Distributed by:
Endoscopic Concepts Inc.	ConMed™ Aspen Surgical Systems
Mendon, MA 01756	Utica, NY 13501
K943976	K933456

Product Description:

The ECI Sabre BT™ Blunt-Tip Surgical Trocar is a single-use, disposable device consisting of a smooth (non-threaded), plastic cannula which is available with an inner diameter of 5, 10 or 12mm. The blunt-tipped trocar is a multi-piece assembly consisting of a plastic handle, and a smooth, rounded plastic tip. This device is intended for use in laparoscopic procedures where the initial incision has been made surgically. The trocar's blunt, atraumatic tip gently moves aside the internal viscera when the device is inserted through the incision site.

Because the OD of the cannula is non-threaded, the device is supplied with an adjustable plug or "olive" which is secured to the patient's skin using sutures placed through the device's "tie posts." The olive has a silicone inner lock ring which firmly grasps the cannula OD when the device is manually tightened.

Indications for Use:

The ECI Sabre BT™ Blunt-Tip Surgical Trocar is indicated for use during endoscopic surgical procedures to establish a pathway for instrumentation and permit maintenance of insufflation.

Biocompatibility:

The following biocompatibility tests were performed on the proposed device:

1. Cytotoxicity Test
2. USP Intracutaneous Toxicity Test
3. Guinea Pig Maximization (Kligman) Sensitization Test

Conclusion:

Based on the indications for use, technological characteristics and performance testing, the ECI Sabre BT™ Blunt-Tip Surgical Trocar has been shown to be safe and effective for its intended use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Pamela L. Papineau
Consultant for Endoscopic Concepts, Inc.
c/o Delphi Medical Device Consulting
50 Brewster Street
Pawtucket, Rhode Island 02860

Re: K980804
Trade Name: Sabre BT™ Blunt Tip Surgical Trocar
Regulatory Class: II
Product Code: FBQ and KOG
Dated: February 13, 1998
Received: March 2, 1998

Dear Ms. Papineau:

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 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.

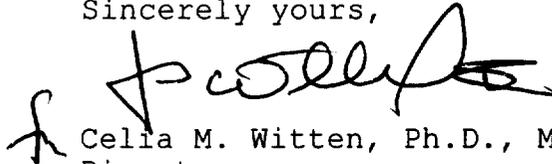
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the 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 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.

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This letter will allow you to begin 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) 594-4595. 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" (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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K980804

Device Name: ECI Sabre BT™ Blunt-Tip Surgical Trocar

Indications for Use:

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(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 Devices
510(k) Number K980804

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____