Adven Medical, Inc.
1001 Slaton Hwy. *(800) 795-8828*
Lubbock, Texas 79404

MAR 1 2002

K013987

510(k) SUMMARY

Classification Name:	Trocar - KAB, KBG, KCI, FBQ, FBM, GCJ, DRC
Common/Usual Name:	Trocar
Trade/Proprietary:	Reprocessed Disposable Trocars
Contact:	Mark W. Aldana

Summary:

AMI intends to market Surgical Trocars that have been reprocessed. "Reprocessed," means all operations performed to render a contaminated single-use device patient ready. AMI is a third party reprocessor. If all protocol parameters are met, AMI will reprocess each disposable trocar up to two times.

Trocars are sold new by the original manufacture to the hospital. The hospital uses the trocars, collects them and ships them to AMI for reprocessing. Trocars are reprocessed by AMI as described in our reprocessing protocol Control Document Number 40005 and returned to the hospital to be reused.

Trocars that do not meet the AMI protocol are rejected. Rejection may occur during the first reprocessing (in which the trocar is not reprocessed at all) or second reprocessing.

AMI believes that reprocessed trocars can be considered "reusable" as defined in the Food and Drug Administration Compliance Policy Guide #7124.16: they are able to withstand the necessary cleaning and sterilization process, the physical characteristics or quality of the device will not be adversely effected, and the device remains safe and effective for its intended use.

AMI reprocesses only trocars that are currently sold on the market and which have met premarket requirements by the original manufacturer for single use.

AMI Reprocessed Trocars addressed in this submission are the same devices that are currently sold on the market as "disposable" by the original manufacturer. The devices identified in this premarket notification are the predicate devices and therefore substantially equivalent to trocars currently on the market.

The concept of marketing reprocessed trocars is similar to the concept of marketing resharpenable surgical saw blades which was found substantially equivalent by FDA in 510(K) 940501 (submitted by Adven Medical, Inc. and cleared on June 28, 1994).

AMI has performed numerous tests to validate its reprocessing protocol.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 2002

Mr. Mark W. Aldana
President
Advèn Medical, Inc.
1001 Slaton Highway
Lubbock, Texas 79404

Re: K013987
Trade/Device Name: Reprocessed Disposable Trocars
Regulation Number: 870.1390
Regulation Name: Trocar
Regulatory Class: II
Product Code: KBG, KCI, FBQ, FBM, GCJ, DCR
Dated: December 3, 2001
Received: December 4, 2001

Dear Mr. Aldana:

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) 594-4659. 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,

for Mark N. Milhauser

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

Enclosure

510)k) Number: K013987

Device Name: Reprocessed Disposable Trocars

Indications For Use:

Reprocessed endoscopic trocars are designed to provide a pathway for entry of minimally invasive instruments to a body organ or cavity during general, abdominal, thoracic, gynecologic or other minimally invasive surgical procedures.

Trocars are single patient used devices.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhauser

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

510(k) Number K013987

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___
(Optional Format 1-2-96)