K012696

# Adven Medical, Inc.

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*Lubbock, Texas 79404*
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FEB 0 4 2002

**510(k) SUMMARY**

Reference: Adven Medical, Incorporated
Section 510(k) Notification
Reprocessed Used Disposable Endoscopic Scissors and Graspers

Classification name: 79GCJ, Manual Laparoscopic Surgical Instruments
79GEI, Endoscopic Electrosurgical Instruments
Common/Usual Name: Laparoscopic/Endoscopic Surgical Instruments
Proprietary Name: Reprocessed Used Disposable Endoscopic Scissors and Graspers
Establishment Registration Number: 1649663

AMI intends to market Endoscopic Scissors and Graspers that have been reprocessed. Reprocessing Endoscopic Scissors and Graspers is performed by AMI to AMI protocol Number 40011. "Reprocessed," means all operations performed to render a contaminated single-use device patient ready (*Enforcement Priorities for Single-Use Devices Reprocessed by Third Party Reprocessors and Hospitals.*

Endoscopic Scissors and Graspers are sold new by the original manufacturers to the hospital. The hospital uses the Endoscopic Scissors and Graspers, collects them and ships them to AMI for reprocessing. Endoscopic Scissors and Graspers are reprocessed by AMI as described in our reprocessing protocol Control Document Number 400011, and returned to the hospital to be reused as a single-use device again.

Endoscopic Scissors and Graspers that do not meet the AMI protocol are rejected. Rejection may occur during the first reprocessing (in which the device is not reprocessed at all) or anytime during subsequent reprocessings.

Endoscopic Surgical Scissors and Graspers are hand-manipulated devices, with and without electrocautery capability; and with and without rotation capability. They are designed for use during minimally invasive surgical procedures and are equipped with elongated shafts to fit through the surgical trocar cannula.

Adven Medical, Inc., Reprocessed Endoscopic Scissors and Graspers are substantially equivalent to Ethicon Endo-surgery Disposable Endoscopic Scissors and Graspers, currently marketed new by Ethicon under 510(k) Number K960933.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 4 2002

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

Re: K012696
Trade/Device Name: Reprocessed Used Disposable Endoscopic Scissors and Graspers
Regulation Number: 878.4800, 884.1720
Regulation Name: Manual surgical instrument for general use
Gynecologic laparoscope and accessories
Regulatory Class: II
Product Code: MDM, HET
Dated: December 3, 2001
Received: December 5, 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,

Miriam C. Provost
for 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: K012696

Device Name: Reprocessed Used, Disposable Endoscopic Scissors and Graspers

Indications For Use:

Endoscopic scissors and graspers are instruments that have a 5 to 10 mm diameter insulated shaft designed for use through surgical trocars. Endoscopic scissors and graspers, in conjunction with trocars, are used in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissections and transection of tissue.

AMI intends to reprocess scissors and graspers. Reprocessing includes all the steps performed to make a contaminated single use device patient ready.

Only Ethicon Endo-Surgery disposable scissors and graspers, that are currently sold on the market (which have met premarket requirements by the original manufacturer for single use) will be reprocessed by AMI.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012696

Prescription Use X
(Per 21 CFR 801.109)

OR

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