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## 510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K081398

1. **Submitter's Identification:**

| | |
|---|---|
| **Contact:** | Mike Hoftman |
| **Company Name:** | Advanced Medical Innovations |
| **Address:** | 9410 De Soto Avenue, Bldg J |
| | Chatsworth, CA 91311 |
| *Tel:* | 818-701-7180 |
| **Fax:** | 818-701-9708 |
| **Date Prepared:** | February 3, 2009 |

2. **Name of the Device:** Advanced Medical Innovations Disposable Trocars and Laparoscopic Accessories

   These disposable devices include: Monopolar Scissors, Maryland Dissecting Forceps, Straight Grasping Forceps, Straight Grasping Forceps with Ratchet, Lapclinch with Ratchet, Rat Tooth Lapclinch with Ratchet, Babcock, Suction Irrigation Set, Trocars (Auto Shield, Hasson, Secondary and Dilating Tip), Veress Needles, Flip Top Reducer and Laparoscopic Smoke Filter.

3. **Common Name:** Electrosurgical, Cutting & Coagulation & Accessories
   **Regulation:** 878.4400
   **Product Code:** GEI

   **Common Name:** Laparoscopic, Gynecologic and accessories
   **Regulation:** 884.1720
   **Product Code:** HET

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4. **Predicate Device Information and Comparison**:

| Device Description | Predicate Device | 510(k) Number | Comparison |
|---|---|---|---|
| American Medical Innovations Disposable Trocars and Laparoscopic Accessories | VECTEC Bioparc, France. VECTEC Disposable Trocars and Laparoscopic Accessories | K071976 | Both our subject device and the predicate device are similar in their basic characteristics. |
| Scissors, Forceps, Dissectors, Hook, Lapclinch, Babcock | Applied Medical Resources Corp. | K040295 & K062169 | The predicate device is basically identical to our subject device with the exception of the tip design which is based on physician's preference |
| Suction Irrigation Set | Conmed . Gleeson FloVac Hand controlled Suction Irrigation Instrument. | K940439 | The subject device(s) are basically identical to the predicate device with respect to technological characteristics and function. |
| Veress Needles | Northgate Technologies, Inc Veress Needle | K971837 | The predicate device is basically identical to the subject device. |
| Dilating Tip Trocars, Autoshield Trocars and Hasson Trocars | Ethicon Endo-Surgery Inc - ENDOPATH Trocar | K020428 | Both our subject device and the predicate device are basically identical. |
| Flip Top Reducer | Ethicon, Inc. Endopath (Disposable Surgical Trocar Reducer | K904907 | Both our subject device and the predicate device are basically identical. |
| Secondary Trocar | Pilling Weck Secondary Trocar with a plastic Sleeve and Insufflation Port | K964450 | Both our subject device and the predicate device are basically identical. |

| | | | |
|---|---|---|---|
| Smoke Filter | Pall Medical Laparoscopic Smoke Filtration System | K992361 | Both our subject device and the predicate device are basically identical. |

5. **Device Description**:

The Advanced Medical Innovations Disposable Trocars and Laparoscopic Accessories can be used in a variety of procedures (general, vascular, gynecological and surgical procedures) to cut, dissect, manipulate and/or cauterize various tissues. Trocars are sterile, single-use devices that allow visualization of body cavities and use of the laparoscopic accessories.

The accessory devices are disposable, single use, individually packaged devices that are composed of biocompatible materials. Scissors, forceps, and dissectors have a handle attached to an insulated shaft with different tips, which allows the shaft and tip to rotate. They include a male cautery connector when attached to standard monopolar cautery cables and their generators. All devices are sterilized using a traditional, validated gamma procedure per AAMI/ISO International standard 11137 (EN 552) to a SAL of 10-6.

6. **Intended Use/Indications for Use**

The Advanced Medical Monopolar Scissors, Maryland Dissecting Forceps, Lap Clinch, Rat Tooth LapClinch, Babcock, Straight Grasping Forceps with Ratchet are indicated for use in gynecological and general endoscopic procedures for mobilization and transection of tissues. The device with a 5mm diameter insulated shaft has a male cautery connection on top of the handle and may be used for monopolar cautery when attached to standard cautery cables and their generators

The Advanced Medical Reducer has application in gynecologic laparoscopy and other abdominal procedures and is designed to be used with the Advanced

Medical Disposable Surgical Trocar to allow the surgeon to insert undersized instruments through the Trocar without losing insufflation.

The Advanced Medical Laparoscopic Smoke Filter is intended for the filtration of contaminants from smoke, generated during laparoscopic surgery, which can contain volatile organic products of combustion (including those which are perceived as odor) and particulates (including cellular debris, bacteria and viruses).

The Advanced Medical Hasson Trocar and Dilating Tip Trocar has application in thoracic, gynecologic laparoscopy, and other abdominal procedures to establish a path of entry for endoscopic instruments.

The Advanced Medical Shielded Trocar has application in thoracic, gynecologic laparoscopy, and other abdominal procedures to establish a path of entry for endoscopic instruments. Instruments provided with a stopcock are intended for insufflation of the operative space when the trocar is in place.

The Advanced Medical Secondary Trocar and Sleeve with Insufflation Port are manual surgical instruments used to support a cut down (lap approach).

The Secondary Trocar is used in endoscopic surgery (abdominal and thoracic) for incision and peritoneal access for positioning of the hollow sleeve. Once the trocar is removed, the port of entry provided by the sleeve, through the cap, is used with manual surgical instruments, endoscopic instruments, laparoscopes and probes. There is a seal on the cap which closes the port of entry.

The Advanced Medical Stainless Steel Veress Needle is for the initial induction of pneumoperitoneum.

The Advanced Medical Suction/Irrigation Set is intended for use in endoscopic procedures such as laparoscopy, pelviscopy, and thorascopy, for suctioning of large clots, retrieving spilled stones, high flow irrigation and hydro-dissection.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Advanced Medical disposable trocars and laparoscopic accessories met the electrical, safety, EMC, and applicable testing requirements of IEC 60601-2-2:2006 4th Edition .

None of the testing demonstrated any design characteristics that violated the requirements of the standards or resulted in any safety hazards.

8. **Discussion of Clinical Tests Performed:**

Clinical testing was not conducted.

9. **Conclusions:**

Based on the information provided in this submission we conclude that the Advanced Medical Disposable Trocars and Laparoscopic Accessories are substantially equivalent to the predicates and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Advanced Medical Innovations, Inc.
% MDI Consultants, Inc.
Ms. Maria F. Griffin
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K081398
Trade/Device Name: Advanced Medical Disposable Trocar and Laparoscopic Accessories
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI, HET, GCJ
Dated: January 28, 2009
Received: January 29, 2009

Dear Ms. Griffin:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Attachment A

**Indications for Use**



**510(k) Number (if known):** K081398

**Device Name:** Advanced Medical Disposable Trocar and Laparoscopic Accessories

**Indications For Use:**

The Advanced Medical Monopolar Scissors, Maryland Dissecting Forceps, Lap Clinch, Rat Tooth LapClinch, Babcock, Straight Grasping Forceps with Ratchet are indicated for use in gynecological and general endoscopic procedures for mobilization and transection of tissues. The device with a 5mm diameter insulated shaft has a male cautery connection on top of the handle and may be used for monopolar cautery when attached to standard cautery cables and their generators

The Advanced Medical Reducer has application in gynecologic laparoscopy and other abdominal procedures and is designed to be used with the Advanced Medical Disposable Surgical Trocar to allow the surgeon to insert undersized instruments through the Trocar without losing insufflation.

The Advanced Medical Laparoscopic Smoke Filter is intended for the filtration of contaminants from smoke, generated during laparoscopic surgery, which can contain volatile organic products of combustion (including those which are perceived as odor) and particulates (including cellular debris, bacteria and viruses).

The Advanced Medical Hasson Trocar and Dilating Tip Trocar has application in thoracic, gynecologic laparoscopy, and other abdominal procedures to establish a path of entry for endoscopic instruments.

**Prescription Use** __X__ **(Per 21 CFR 801 Subpart D)** **OR** **Over-The Counter Use**_____ **(21 CFR 807 Subpart C)**

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

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Mark A Melkerson

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

**510(k) Number** K081398

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Attachment A

**Indications for Use**



**510(k) Number (if known):** K081398

**Device Name:** The Advanced Medical Disposable Trocar and Laparoscopic Accessories

**Indications For Use:**

The Advanced Medical Shielded Trocar has application in thoracic, gynecologic laparoscopy, and other abdominal procedures to establish a path of entry for endoscopic instruments. Instruments provided with a stopcock are intended for insufflation of the operative space when the trocar is in place.

The Advanced Medical Secondary Trocar and Sleeve with Insufflation Port are manual surgical instruments used to support a cut down (lap approach).

The Secondary Trocar is used in endoscopic surgery (abdominal and thoracic) for incision and peritoneal access for positioning of the hollow sleeve. Once the trocar is removed, the port of entry provided by the sleeve, through the cap, is used with manual surgical instruments, endoscopic instruments, laparoscopes and probes. There is a seal on the cap which closes the port of entry.

The Advanced Medical Stainless Steel Veress Needle is for the initial induction of pneumoperitoneum.

The Advanced Medical Suction/Irrigation Set is intended for use in endoscopic procedures such as laparoscopy, pelviscopy, and thorascopy, for suctioning of large clots, retrieving spilled stones, high flow irrigation and hydro-dissection.

**Prescription Use** __X__ **(Per 21 CFR 801 Subpart D)** **OR** **Over-The Counter Use**_____ **(21 CFR 807 Subpart C)**

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

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Mark N Milhern

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

**510(k) Number** K081398