510(k) SUMMARY

AUG 2 3 2010

510(K) NUMBER: K093783

SUBMITTED BY:

Innovia LLC
12415 SW 136 Avenue
Unit 3
Miami, FL 33186
305-378-2651

CONTACT PERSON:

Bruce Weber
Vice President, Clinical, Regulatory and Quality Assurance

DATE OF PREPARATION: July 13, 2010

NAME OF DEVICE: Laparoscopic Access Port

CLASSIFICATION: Laparoscope, General & Plastic Surgery (21CFR 876.1500)

TRADE NAME: InnoPort™ Laparoscopic Access Port

PREDICATE DEVICE: Innovia InnoPort™ Laparoscopic Access Port (K090677)

INTENDED USE: The InnoPort Laparoscopic Access Port is a sterile, single use device, intended for use as a multiple instrument and/or camera port during minimally invasive laparoscopic abdominal surgery.

DEVICE DESCRIPTION: The InnoPort Laparoscopic Access Port is a sterile, single use laparoscopic access device comprised of flexible polymer and a rigid plastic plate. The InnoPort forms a truncated cone approximately 5.0 centimeters long (not including instrument ports), with three individual laparoscopic instrument ports at the larger end. A fourth port connects to the insufflation system to provide intra-abdominal pneumoperitoneum, and a fifth port may be used for intra-procedural smoke removal. The instrument ports are designed to accommodate 5 mm diameter laparoscopic instruments while allowing full maneuverability without loss of pneumoperitoneum. The complete device is designed to be inserted through a single incision into the abdominal cavity for the duration of surgery.

PERFORMANCE DATA SUMMARY: The performance and functional testing of the InnoPort Laparoscopic Access Port included bench and *in vivo* tests to verify its ability to maintain pneumoperitoneum with minimal leakage, allow introduction and manipulation of instruments, and meet performance specifications. The testing demonstrated that the InnoPort Laparoscopic Access Port is substantially equivalent to its predicate device and it introduces no new safety or effectiveness issues when used as instructed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Innovia LLC
% Mr. Bruce Weber
Vice President, Clinical, Regulatory
and Quality Assurance
12415 SW 136 Avenue
Miami, Florida 33186

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Re: K093783
Trade/Device Name: Innovia InnoPort™ Laparoscopic Access Port
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: July 13, 2010
Received: July 14, 2010

Dear Mr. Weber:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

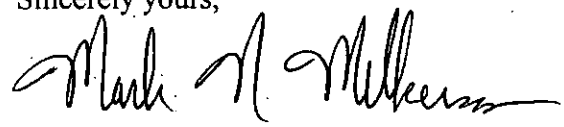
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K093783

Indications for Use

510(k) Number (if known): _____

Device Name: Innovia InnoPort™ Laparoscopic Access Port

Indications for Use:

The Innovia InnoPort™ Laparoscopic Access Device is a sterile, single use device intended for use as a multiple instrument and/or camera port during minimally invasive laparoscopic abdominal surgery.

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mxm

(Division Sign-Off)

Division of Surgical, Orthopedic, and Restorative Devices

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