K101193

PMC
Medical GmbH

>> 510(k) Summary as required by section 807.92 04/15/2010

OCT 18 2010

>>Submission Applicant:
PMC Medical GmbH
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Establishment Registration Number: 3006986250

>>Application Correspondent/Contact:
think!
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>> Device Identification:

Trade name: PMC Laparoscopic instruments

Common name: Laparoscopes / Endoscopes

Classification name: Laparoscope, general & plastic surgery, Endoscope and accessories, Review Panel General & Plastic Surgery (21 CFR 876.1500, GCJ)

>> Predicate Device Information:

510(k)-Number: K012660, GIMMI ALPHA® Instruments & Accessories
Firm: GIMMI GMBH

510(k)-Number: K080257, MicroFrance Laparoscopic Manual Surgical Instruments
Firm: MEDTRONIC XOMED, INC.

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>>Description of the Device:

PMC Laparoscopes provide illumination and visualization in diagnostic procedures and in conjunction with laparoscopic instruments (accessories) operative laparoscopic procedures as:
-unexplained pelvic pain (acute, chronic)
-infertility work-up
-tubal sterilization
-diagnosis and/or treatment of ectopic pregnancy
-evaluation, diagnosis and/or treatment of pelvic tumors, incl. myomata (less than 16 weeks gestational size)
-Retrieval of foreign bodies
-determination of the presence and extent of pelvic endometriosis
-determination of the presence and extent of pelvic inflammatory disease (if not in acute stage)
-access to abdomen for surgical procedures such as LAVH
-visualization, diagnosis and/or treatment of perforate abdominal organs

The PMC Laparoscopic instruments contain different components such as scissors, forceps, connections, handles, sheaths, laparoscopes, light adapters, trocars, electrode, and inserts. The instruments are made out of martensitic stainless steel, a standard material for medical devices, and insulation material.

>>Indications for Use:

Laparoscopes are used by surgeons in diagnostic and therapeutic procedures. Laparoscopic minimally invasive procedures are performed in the abdominal cavity by means of small skin punctures that allow the insertion of the laparoscope and laparoscopic instruments.

The PMC Laparoscopic instruments are intended to scrape, cut, grasp, hold, remove, and manipulate tissue, organs or bowel during laparoscopic surgery. The secondary function is to provide monopolar electrocautery capability to dissect and coagulate soft tissue.

>> Technological characteristics compared to the Predicate Devices:

The PMC Laparoscopic instruments are similiar to the Gimmi and Medtronic Xomed products in terms of design, technical characteristics, intended use, indications for use, sterilization, and components of devices. The Laparoscope and the respective laparoscopic instruments are identical to the predicate devices. The PMC product is also similiar to the Gimmi and Medtronic Xomed products in terms of the used material.

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	PMC Laparoscopic instruments New device	MicroFrance Laparoscopic Manual Surgical Instruments K080257	GIMMI ALPHA® Instruments K012660
Diameter Lengths	5mm Tube, 310mm/330mm/336mm various	3mm to 12mm Tube, various from 25cm to 60cm	5mm Tube, various, from 25 cm to 38 cm
Material	Stainless Steel Carbon-fibre Insulation material	Stainless Steel Tungsten (Needle Holders) Insulation material	Stainless Steel Insulation material
Components	Scissors, Forceps, Connections, Handles, Sheaths, Laparoscopes, Light Adapters, Trocars, Electrode, and Inserts	Dismantable and Non-dismantable Insulated and non-insulated Forceps, Probes, Needle Holders, Clamps, Dissectors, Scissors, Knife, Hook, Knot Guide, Retractors, and Blades	Dismantable and Non-dismantable Insulated and non-insulated Forceps, Probes, Needle Holders, Clamps, Dissectors, Scissors, Knife, Hook, Knot Guide, Retractors, Divers and Blades

>> Non-clinical performance data:

PMC certifies compliance with relevant ISO/IEC/EN and other device-related standards.
Moreover bench testing has been performed on the PMC Laparoscopic instruments to demonstrate that the device is substantially equivalent to the predicate devices.

>>Summary:

The presented data that was conducted on the PMC Laparoscopic instruments shows in its results and in comparison to the predicate devices that the product is safe, as effective, and performs as well as or better than the legally marketed device, therefore do not raise any questions regarding safety and effectiveness. The product components which are covered by this 510(k) premarket notification have been successfully tested for biocompatibility, electromagnetic compatibility, functionality and safety according to international standards.

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

PMC Medical GmbH
% think!
Ms. Andrea Pecsi
Schwarzwaldstraße 5
78532 Tuttlingen
Germany

OCT 18 2010

Re: K101193
Trade/Device Name: PMC Laparoscopic instruments
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: September 13, 2010
Received: September 16, 2010

Dear Ms. Pecsi:

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 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

Indication for Use

K101193

510(k) Number (if known): K101193

OCT 18 2010

Device Name:
PMC Laparoscopic instruments

Indications for Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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