Prosurgics Ltd.
Special 510(k)
Freehand Endoscopic Camera Controller

MAY 22 2009

510(k) Summary

(1) Submitter Information

Name: Prosurgics Ltd.

Address:

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2 Arlington Business Park
Bracknell RG12 1 WA
United Kingdom

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Contact Person:
Dr. George Myers (Official Correspondent)
Medsys Inc.
377 Route 17 S
Hasbrouck Heights, NJ 07604
Telephone 201-727-1703
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Date Prepared: February 4, 2009

(2) Name of Device

Trade Name: Freehand
Common Name: Endoscopic Camera Controller
Classification name: Rigid Endoscope Accessory

(3) Equivalent legally-marketed devices.

1. Prosurgics EndoAssist, K043284
2. Computer Motion Inc, Aesop, K972699

(4) Description

Freehand is a modification of Prosurgics EndoAssist. The Freehand is intended for use in minimally invasive laparoscopic, thoracoscopic, urological, gynecological and cardiac surgery where a rigid laparoscope/endoscope is intended for use, and allows the surgeon directly to control movements of a rigid endoscope by head movements. Changes that have been made are to provide simpler control mechanisms that should result in greater reliability, as well as several convenience features. From the surgeon's point of view, the two devices are the same as far as their operation and functions are concerned.

(5) Intended Use

Freehand intended to be used in general thoracoscopy, general cardiothoracic surgery, general laparoscopy, nasopharyngoscopy, ear endoscopy and sinuscopy, where a rigid laparoscope/endoscope is intended for use.
A few examples of the more common endoscopic surgeries are laparoscopic cholecystectomy, hernia repair, fundoplication, splenectomy, appendectomy, hemicolectomy, sympathectomy, lymph node dissection, hysterectomy, gastric banding, gastric by pass, nephrectomy, radical prostatectomy, anterior spinal fusion, decompression fixation, wedge resection, lung biopsy, pleural biopsy, internal mammary artery dissection for coronary artery bypass, coronary artery bypass grafting where endoscopic visualization is indicated, examination of the evacuated cardiac chamber during performance of valve replacement or repair.
The users of FreeHand are general surgeons, bariatric surgeons, gynecologists, cardiac surgeons, thoracic surgeons, orthopedic surgeons, ENT surgeons and urologists.

(6) Performance Data

(a) Non-clinical tests

All aspects of Freehand has been extensively validated. It meets the requirements of IEC 60601-1 (electrical safety) and IEC 60601-1-2 (electromagnetic compatibility).

(b) Clinical tests

Clinical tests are not necessary, since Freehand uses the same technology as the predicate device.

(c) Conclusions

Freehand is equivalent in safety and efficacy to the legally-marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Prosurgics Limited
% Medsys, Inc.
George H. Myers, Sc.D.
377 Route 17 S
Hasbrouck Heights, New Jersey 07604

MAY 22 2009

Re: K090340
Trade/Device Name: Freehand
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: May 5, 2009
Received: May 7, 2009

Dear Dr. Myers:

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 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 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

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

Enclosure

Indications for Use

510(k) Number (if known): K090340

Device Name: Freehand

Indications for Use:

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Freehand is indicated for use in general thoracoscopy, general cardiothoracic surgery, general laparoscopy, nasopharyngoscopy, ear endoscopy and sinuscopy, where a rigid laparoscope/endoscopeis intended for use.

A few examples of the more common endoscopic surgeries are laparoscopic

cholecystectomy

hernia repair

fundoplication

splenectomy

appendectomy

hemicolectomy

sympathectomy

lymph node dissection

hysterectomy

gastric banding

gastric by pass

nephrectomy

radical prostatectomy

anterior spinal fusion, decompression fixation

wedge resection

lung biopsy

pleural biopsy,

internal mammary artery dissection for coronary artery bypass

coronary artery bypass grafting where endoscopic visualization is indicated

examination of the evacuated cardiac chamber during performance of valve

replacement or repair.

The users of EndoAssist are general surgeons, bariatric surgeons, gynecologists,

cardiac surgeons, thoracic surgeons, orthopedic surgeons, ENT surgeons and urologists

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K090340