ARMSTRONG
surgical excellence through robotics

K043284

FEB 25 2005

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17 January 2005

510(k) Summary

Contact: Dr Patrick Finlay, Director

Device Details:
The trade name of the device is EndoAssist
The common name for the device is endoscopic camera manipulator
The classification name is rigid endoscope accessory
The classification group code is GCJ per CFR Section 21 876.1500

Predicate Devices
EndoAssist K973249, AESOP 3000 K972699, Lapman K023735

Description of Device
EndoAssist is a head-controlled Endoscopic camera manipulator. It is intended for use in minimally invasive laparoscopic, thoracoscopic, urological, gynecological and cardiac surgery and allows the surgeon directly to control movements of a rigid endoscope by head gestures.

Intended Use
EndoAssist is indicated for use in general thoracoscopy, general cardiothoracic surgery, general laparoscopy, nasopharyngoscopy, ear endoscopy and sinuscopy, where a rigid laparoscope/endoscope is intended for use.

Technological characteristics compared with predicates
The EndoAssist predicate device described in K973249 is the same device as the applicant device in all material respects. The only difference between K973249 and the present application is the change in Indications for Use. The AESOP 3000 predicate device K972699 performs the same functions, but is controlled by voice commands and is clamped to the side of the operating table. EndoAssist is controleed by natural head movements and is free-standing. The Lapman predicate device K0237352 is controlled by switches inserted into the surgeon's glove. The working volume of Lapman is significantly smaller than that of EndoAssist or AESOP, which limits its area of use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Dr. Patrick A. Finlay
Director
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Re: K043284
Trade/Device Name: EndoAssist
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: January 19, 2004
Received: January 21, 2004

Dear Dr. Finlay:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost

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

Indications for Use

510(k) Number (if known): K043284

Device Name: EndoAssist

Indications for Use:

EndoAssist is indicated for use 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 EndoAssist are general surgeons, bariatric surgeons, gynecologists, cardiac surgeons, thoracic surgeons, orthopedic surgeons, ENT surgeons and urologists

** In this context "laparoscopic" is taken to embrace the use of a rigid endoscope in any part of the body*

Prescription Use ___YES____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __NO_____ (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)

Miriam C Provost

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

510(k) Number K043284