K082233

510(k) Summary
ViKY

DEC 1 8 2008

The summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92.

510(k) Submitter:
EndoControl
5 avenue du Grand Sablon
38700 La Tronche
France
Phone : +33 476637583
Fax : +33 476637592

Contact Name:
Carine Huguel
carine.huguel@endocontrol-medical.com

Date Prepared:
December 12th, 2008.

Proposed Device:

Trade Name:	ViKY
Common Name:	Endoscope Holder
Classification Name:	General & Plastic Surgery, 21 CFR PART 876.1500
Device Class:	II
Product Code:	GCJ

Predicate Device:
The ViKY System is substantially equivalent to AESOP 3000 System and accessories that were cleared by FDA under K972699 on December 17, 1997, and to GMP|Surgical Solutions Inc. Laparocision™ Scope Controller System that was cleared by FDA under K050027 on January 27, 2005.

Device Description:
ViKY is a motorized endoscope holder for thoracic, abdominal, and pelvic minimally invasive procedures. ViKY is maintained by a dedicated arm attached to the table. It is moved according to surgeon orders by means of either a foot controller or a voice controller, in caudal, cranial and lateral directions, as well as zoom in and zoom out of the field.

Intended Use:
The ViKY System is a motorized device whose intended use is to allow a surgeon to hold and position a rigid endoscope during endoscopic surgical procedures. Its light architecture allows the ViKY System to be maintained above the patient by a dedicated arm attached to the table. The ViKY System movements are controlled by the surgeon either by a foot controller or a voice controller.

Indications for Use:
The ViKY System is indicated for thoracic and laparoscopic minimally invasive procedures for the purpose of holding and controlling the movement of standard rigid endoscopes within surgical cavities during endoscopic surgery.

Comparison of Technological Characteristics:
The ViKY System and the predicate devices have electronic components to control the position of laparoscopes during laparoscopic surgical procedures. ViKY System has a light architecture that allows it to be attached to the table by a dedicated arm, which is similar to both LAPAROCISION (K050027), and AESOP (K972699). The main technological difference is that the ViKY System is sterilized, although the predicate devices are protected by a sterile covers. The differences in technology do not raise any significant questions or issues regarding the safety and effectiveness of the device.

Testing:
Electrical Safety is tested in accordance with the following standards:

- EN 60601-1:1990, Medical electrical equipment - Part 1: General requirements for safety
- UL 60601-1:2003, Medical Electrical Equipment -Part 1: General Requirements for Safety
- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.

Electromagnetic Compatibility (EMC) is tested in accordance with the following standards:

- IEC 60601-1-2, (Second Edition, 2001), Medical Electrical Equipment - Part 1-2: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests.

In addition, summaries of testing on animals and clinical experience with the system were provided.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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EndoControl
% Ms. Carine Huguel
Quality Manager
5 Avenue Du Grand Sablon
La Tronche 38700
France

Re: K082233
Trade/Device Name: ViKY
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: December 12, 2008
Received: December 15, 2008

Dear Ms. Huguel:

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

Indications for use

510(k) Number:
K082233

Device Name:
ViKY

Indications For Use:
The ViKY System is indicated for thoracic and laparoscopic minimally invasive procedures for the purpose of holding and controlling the movement of standard rigid endoscopes within surgical cavities during endoscopic surgery.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for

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

510(k) Number K082233