K122820

510(k) Summary

JUN 18 2013

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

Date prepared
May 2013

510(k) submitter
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Subject device

Trade name	ViKY UP
Common name	Holder, Manipulator, Positioner, Arm
Regulation number	Unclassified
Regulation name	Unclassified
Regulatory class	Unclassified
Product code	LKF

Predicate devices
- ViKY Endoscope Holder (K082233), EndoControl
- Probe Holder System (K071405), Intuitive Surgical

Purpose
The purpose of this 510(k) submission is to demonstrate that the subject device is substantially equivalent to the above listed predicate devices.

Device description
ViKY UP is a motorized uterine manipulator positioner for computer-controlled laparoscopic hysterectomies. ViKY UP holds and moves the uterine manipulator in three directions according to surgeon orders by means of either a foot controller or a voice controller.

Use of the ViKY UP allows surgeon to remotely gain control on uterine manipulator positioning from his operating position.

The ViKY UP includes two attachment mechanisms: one at its first end for mounting the system to the operating room table and the other at the second end for securely grasping a uterine manipulator.

The ViKY UP remains external to the patient's body at all times and can be steam sterilized.

Indications for use
The ViKY UP device is indicated for computer-controlled laparoscopic hysterectomies (such as da Vinci-assisted laparoscopic hysterectomies) for the purpose of holding and controlling the movement of a uterine manipulator.

Comparison to predicate devices
The Probe Holder System uses hydraulic energy whereas ViKY EP and ViKY UP use electrical energy. The three systems include a foot pedal to actuate the mechanism, ViKY EP and ViKY UP also include voice actuation. ViKY EP and ViKY UP can be remote controlled, the Probe Holder System cannot.

Based upon available technical information, intended use, performance information and method of use provided in this pre-market notification, the ViKY UP device is substantially equivalent to Probe Holder System (K071405) and has the same technological characteristics as the ViKY EP device (K082233).
Compared to both predicate devices, ViKY UP does not create new risk, does not raise new issues on safety and effectiveness.

Performance data
Design analysis and testing has been conducted to confirm that basis functional characteristics of the subject device are substantially equivalent to those of the predicate devices.
Use has been validated through bench testing and clinical testing that demonstrated that the ViKY UP device can be used safely and efficiently for the claimed intended use.

Non-clinical tests
Non-clinical testing consisted of bench and anatomical tests.
These tests validated usability and ergonomy of the ViKY UP device and confirmed that basic functional characteristics are in compliance with marketing system requirements, and that design output meets the design input requirements.

Clinical tests
A clinical study has been carried out on 30 patients candidate for laparoscopic hysterectomy procedure and aged between 18 and 80. Exclusion criteria were principally comprised of patients for whom anatomy precludes the use of a uterine manipulator.
The primary objective was to evaluate the safety and effectiveness of using the ViKY UP device to manipulate the uterine manipulator during computer-controlled laparoscopic hysterectomies.
Secondary objectives included set up time and overall procedural impact of the use of the ViKY UP device for uterine manipulation.
No adverse effects or complication were observed during the study. The results showed safety and effectiveness of the device for computer-controlled laparoscopic hysterectomies and did not raise any issue.

Conclusion
Data included in this submission demonstrate that the evaluation of ViKY UP does not raise any additional concerns regarding safety and effectiveness and can be considered substantially equivalent to 510(k) cleared predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Letter dated: June 18, 2013

EndoControl
% Ms. Carine Huguel
5 avenue du Grand Sablon
38700 La Tronche, France

Re: K122820
Trade/Device Name: VIKY UP
Regulatory Class: Unclassified
Product Code: LKF
Dated: April 30, 2013
Received: May 23, 2013

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. 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 -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use statement

510(k) number
K122820

Device name
ViKY UP

Indications for use
The ViKY UP device is indicated for computer-controlled laparoscopic hysterectomies (such as da Vinci-assisted laparoscopic hysterectomies) for the purpose of holding and controlling the movement of a uterine manipulator.

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

Joshua C. Nipper -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K122820