K092684

CardinalHealth

Cardinal Health
1430 Waukegan Road
McGaw Park, Illinois 60085-6787
847.578.6610
FAX: 847.785.2506

JAN 22 2010

SMDA REQUIREMENTS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Laparoscopic Retractors

Sponsor:	Cardinal Health 1430 Waukegan Road MPKB McGaw Park, IL 60085
Regulatory Affairs: Contact	Sharon Nichols
Telephone:	(847) 578-6610
Date Summary Prepared:	August 2009
Common Name:	Laparoscopic Retractors
Regulation Description:	Endoscope and Accessories
Device Classification name	Laparoscope, General and Plastic Surgery
Device Class and Regulation Number:	II 21 CFR §876.1500
Procode:	GCJ
Predicate Devices:	K933008, Laparoscopic Retractors and Scraper K930667, Reusable Laparoscopic Instruments
Description:	The proposed Laparoscopic retractors are inserted through the trocar cannula and into the abdomen in order to provide visualization during laparoscopic surgery by retracting and manipulating organs at the surgical site.

Intended Use:	Laparoscopic Retractors are designed to retract or elevate organs and tissues to provide better visualization access to surgical sites during minimally invasive laparoscopic procedures.
Summary of Technological Characteristics:	The proposed device and the predicate devices are composed of the same or similar design, materials and manufacturing characteristics.
Summary of testing:	All materials used in the fabrication of the Laparoscopic Retractors were evaluated through biological qualification safety tests as outlined in ISO 10993 Part-1 "Biological Evaluation of Medical Devices". These materials also were evaluated in accordance with industry recognized test methods and were found to be acceptable for the intended use.
Non-Clinical Testing:	Performance testing demonstrated that the proposed device is substantially equivalent to the currently marketed predicate devices with regard to functional characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

JAN 22 2010

Cardinal Health
% Ms. Sharon Nichols
Regulatory Affairs Manager
1430 Waukegan Road MPKB
McGaw Park, Illinois 60085

Re: K092684
Trade/Device Name: Laparoscopic Retractors
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: March 21, 2010
Received: March 21, 2010

Dear Ms. Nichols:

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/cdrh/mdr/ 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/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

K092684

1430 Waukegan Road
McGaw Park, Illinois 60085-6787
847.578.6442
FAX: 847.785.2506

Indication for Use

510(k) Number (if known):

Device Name: Laparoscopic Retractors

Indications For Use: Laparoscopic Retractors are designed to retract or elevate organs and tissues to provide better visualization access to surgical sites during minimally invasive laparoscopic procedures.

Prescription Use _X__ or Over-The Counter Use _____

(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K092684

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