ENCISION

K090979

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510(k) Summary

DATE: April 3, 2009

510(k) Submitter:
ENCISION INC.
6797 Winchester Circle
Boulder, CO 80301 USA
Establishment Registration: 1722040

MAY 28 2009

Contact Person:
Judith V. King, VP Regulatory Affairs and Quality Assurance
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Device Name: Disposable Handle Assemblies

Common name: Endoscope and Accessories

Classification: CFR Section: 876.1500. Secondary classification: 884.1720

Class: II

Product Code: GCJ

Predicate Devices:

Trade, Proprietary or Model Name	**Manufacturer**
Shielded Laparoscopic Monopolar Electrodes	Encision Inc.
"Take Apart®" Insulated Forceps, Biopsy Forceps, Scissors	Karl Storz Endoscopy America Inc.
Laparoscopic Scissors	Applied Medical Resources Corp.
Endopath Endoscopic Instruments	Ethicon Endo-Surgery, Inc.

Description of Devices:
The DH0100 series and DH0500 series Disposable Handle Assemblies are fully disposable surgical instruments which are packaged for use without additional setup. The instruments fit standard 5.5mm cannulas. The Disposable Handle Assemblies are available in various operative lengths and styles. Tip styles include scissors, and double action and single action forceps and jaws for dissection or grasping. The handle and trigger open and close the working tip of the instrument. The rotation knob turns to allow 360°orientation of the tip as the surgeon prefers.

This device does not transmit electrosurgical energy. There is no connection for monopolar or bipolar output from a generator. However, the shaft is insulated, in the event the instrument comes into contact with an active instrument, to prevent stray energy burns.

The assembly is supplied sterile and is not intended for more than one use.

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Intended Use:

The Encision Disposable Handle Assemblies are for use during minimally invasive surgical, laparoscopic and endoscopic procedures performed in general surgery, obstetrics/gynecology and gastroenterology/urology.

Contraindications

- These instruments have not been shown to be effective for tubal sterilization procedures, and should not be used for these procedures.
- These instruments are not intended for use when minimally invasive techniques are contraindicated.

Technological Characteristics:

The Encision Disposable Handle Assemblies incorporate the same technological characteristics as the predicate devices, with the exception that no option is provided for connection to a high frequency electrosurgical energy source. The cutting and tissue manipulation features, however, perform in an equivalent manner, and the handle articulation is transmitted to the tips in the same way. The shaft of the instrument is also insulated. The single use device is packaged assembled and shipped sterile.

Non-clinical Performance Testing:

Performance of the devices' articulating functions, and shaft insulation dielectric withstand, have been verified by bench testing.

Materials were selected and verified to meet the biocompatibility requirements of the applicable ISO 10993 series of standards.

Conclusions:

The Encision Disposable Handle Assemblies are safe and effective and are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 2009

Encision, Incorporated
% Ms. Judith V. King
Vice President Regulatory Affairs & Quality Assurance
6797 Winchester Circle
Boulder, Colorado 80301

Re: K090979
Trade/Device Name: Disposable Handle Assemblies
Regulation Number: 21 CFR 884.1720
Regulation Name: Gynecologic Laparoscope and Accessories
Regulatory Class: II
Product Code: HET, GCJ
Dated: April 3, 2009
Received: April 7, 2009

Dear Ms. King:

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 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,

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): K090979

Device Name: Disposable Handle Assemblies

Indications for Use:

The Encision Disposable Handle Assemblies are used for minimally invasive surgical, laparoscopic and endoscopic procedures performed in general surgery, obstetrics/gynecology and gastroenterology/urology.

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)

Neil R. Ogden for mkm

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

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