ENCISION® K091074

510(k) Summary

DATE: 7/13/09

AUG 17 2009

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

Contact Person:
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Device Name: AEM Disposable Electrodes and AEM Disposable Handpieces

Common name: Device, Electrosurgical, Cutting and Coagulation and Accessories

Classification: CFR Section: 878.4400

Class: II

Product Code: GEI

Predicate Device:

Electrodes

Trade, Proprietary or Model Name	Manufacturer
Model ES0300 series AEM Disposable Electrodes	Encision Inc.

Handpieces

NA – no change

Description of Devices:

The AEM Disposable Electrode and the AEM Disposable Handpiece connect to a compatible electrosurgical generator via an adapter on the ENCISION AEM Monitor. The handpiece has foot switching and hand switching versions. The electrodes and handpieces are single use products, which are provided sterile. They are designed not to be re-sterilized.

The AEM Monitoring System, including the electrodes and handpieces, are designed to minimize the likelihood of stray energy injuries caused by active insulation failure or capacitive coupling. The monitor does this by shutting down the ESU when excessive current is returned via the shield circuit which extends to near the tip of the electrode.

The electrodes, which consist of an insulated tip, shaft with locking knob, and AEM shield assembly, are available in various tip styles. The material of the molded tip

insulation has been changed. The electrode has an inner insulation between the active conductor and shield tube, as well as a secondary outer insulation on the outside of the electrode shaft.

The electrodes snap into the handpiece. The electrodes may be removed from the handpiece and replaced with another electrode within the sterile field.

The electrode can rotate freely or be locked in one of multiple orientations relative to the handpiece, as preferred by the surgeon.

Intended Use:

AEM Disposable Electrodes and AEM Disposable Handpieces are electrosurgical accessories intended, by use of monopolar high-frequency electrical current from compatible electrosurgical generators, for ablation, removal, resection and coagulation of soft tissue where associated hemostasis is required in open, endoscopic and laparoscopic surgical procedures.

The devices are intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

AEM instruments incorporate the use of AEM technology and are intended for use with the Encision AEM Monitoring System and electrosurgical generators having compatibility with the AEM Monitor.

Technological Characteristics:

The Encision AEM Disposable Electrodes with new tip insulation material incorporates the same technological characteristics as the predicate device for delivery of the ESU high frequency current, consisting of insulated conductors and shafts with appropriately shaped tips for electrosurgery.

There is no change to the AEM Disposable Electrodes' AEM shielding function which diverts stray energy from the shaft of the instrument and is monitored by the Encision AEM Monitor, via the AEM Handpiece cable.

Non-clinical Performance Testing:

The tip insulation material has no effect on the specified performance requirements of the device. There are no industry or international standards that apply to the tip insulation. Suitability of the new material for the tip insulation has been verified by biocompatibility testing per ISO 10993-1. Sterilization Validation has been performed per AAMI/ANSI/ISO 11737-1 and -2.

Conclusions:

The AEM Disposable Electrodes are safe and effective and are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

AUG 17 2009

Encision, Inc.
% Intertek Testing Services NA, Inc.
Mr. Daniel W. Lehtonen
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K091074
Trade/Device Name: AEM Disposable Electrodes and AEM Disposable Handpieces
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories.
Regulatory Class: Class II
Product Code: GEI
Dated: July 29, 2009
Received: August 5, 2009

Dear Mr. Lehtonen:

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/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
Director
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): _____

Device Name: AEM Disposable Electrodes and AEM Disposable Handpieces

Indications for Use:

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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)

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

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