K093622

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510(k) Summary

DATE: August 13, 2010

AUG 20 2010

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

Contact Person:
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Device Name: AEM® Monitoring System

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

Classification: CFR Section: 878.4400

Class: II

Product Code: GEI

Predicate Devices:

Trade, Proprietary or Model Name	Manufacturer
Electroscope Monitor EM-1	Encision Inc. (was Electroscope, Inc.)
Active Electrode Monitoring (AEM) System	Encision Inc.

Regulatory Background:

The AEM Monitor, under the name Electroscope Monitor EM-1, received 510(k) premarket clearance via K913625 on December 30, 1991.

The AEM Monitoring System, including the AEM Monitor, was modified for use with non-CQM patient return electrodes and received 510(k) premarket clearance via K072789 on May 2, 2000. However, this version is no longer marketed.

Reason for Submission:

The purpose of this submission is to specify the requirements for electrosurgical instruments to be compatible for use with the AEM Monitoring System. Additionally, incremental change to the system since the original substantial equivalence determination will be documented.

The labeling currently states that Encision AEM Laparoscopic Instruments are to be used with the AEM Monitoring System. However, the requirements for AEM technology can be specified to allow the technology to be licensed to other manufacturers. (AEM is the Encision trademarked name for its patented patient safety technology.) Such cords and instruments can be demonstrated to be compatible with the AEM Monitor to make an effective AEM Monitoring System.

Intended Use:
The Encision AEM Monitoring System is an accessory for use with electrosurgical generators and electrodes that is designed to safely deliver electrosurgical energy and to prevent injury caused by insulation failure and capacitive coupling.

The AEM Monitoring System consists of two distinct functions:

- Active electrode monitoring is intended to control stray monopolar energy caused by insulation failure and capacitive coupling in surgical instruments on the shaft of the instrument.
- End point monitoring is intended to aid the surgeon in determining the end point of bipolar electrosurgical desiccation.

Contraindications:

None

Device Description:

The Encision AEM Monitoring System, consisting of the AEM Monitor and accessories, is designed to safely deliver electrosurgical energy and to prevent injury caused by insulation failure and capacitive coupling. The AEM Monitoring System consists of two distinct functions:

1. End point monitoring is intended to aid the surgeon in determining the end point of bipolar electrosurgical desiccation.

   The end point monitor displays the electrosurgical current being delivered during bipolar coagulation. At the point where the tissue or vessel is no longer conductive, the meter will display zero or near zero current. An audible indicator of current, presented as a variable click rate, can also be turned on. An optional remote display is also available.

   There is no change to the end point monitoring function.

2. Active electrode monitoring is intended to control stray monopolar energy caused by insulation failure and capacitive coupling in surgical instruments on the shaft of the instrument.

   The active electrode monitoring is performed by measuring the current in the shield of the AEM electrosurgical instrument. The internal conductive shield also diverts capacitivley coupled energy back to the generator, away from the patient. If excessive magnitude or a quality indicative of a sparking condition is detected, an indicator is lit on the monitor front panel and the signal inhibits the ESU (electrosurgical unit) output using the ESU contact quality monitoring circuit.

   Connection is made to the ESU contact quality monitoring circuit via a jumper cord. A cord connects the AEM instrument to the monitor and to the ESU output via an adapter. Setup indicators are driven by isolating continuity monitors. These provide checks to ensure the adapters and cable assembly are properly connected.

   AEM monitor models, cables and adapters are available for mechanical and electrical compatibility with various ESUs, as well as for footswitching and handswitching monopolar instruments, and bipolar instruments. Minor mechanical and electrical changes may be made to optimize interface with compatible ESUs and instruments, which do not affect the safety and efficacy of the system.

   There is no change to the active electrode monitoring function, including the detection circuitry and instrument interface.

The AEM Monitor Operator/Service Manual is being modified to allow use of the AEM Monitoring System with non-Encision AEM instruments.

Criteria have been defined for electrosurgical instruments using AEM technology to allow compatibility with the monitor. These instruments can be supplied by Encision, or by other manufacturers.

These criteria are met by existing Encision monopolar instruments, covered by 510(k)s K912780 and K091074. Additional instruments may be released by Encision or by other manufacturers (subject to patent requirements and premarket clearance for the instruments) without substantially affecting the design of the AEM Monitor.

The Encision AEM Monitoring System meets applicable industry and international standards for electrosurgical accessories.

Technological Characteristics:
The technological characteristics of the AEM Monitoring System are unaffected by the change in labeling.

Non-clinical Performance Testing:
The AEM Monitoring System essential performance has been verified with representative electrosurgical units and with an instrument representative of the worst case criteria for AEM technology.

Conclusions:
The Encision AEM Monitoring System is safe and effective and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Encision, Inc.
% Ms. Judith V. King
Vice President, Regulatory Affairs
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6797 Winchester Circle
Boulder, Colorado 80301

AUG 20 2010

Re: K093622
Trade/Device Name: AEM® Monitoring System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 17, 2010
Received: August 17, 2010

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

Enclosure

K093622

Indications for Use

510(k) Number: K093622

Device Names:
AEM® Monitoring System

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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

510(k) Number K093622