K122383

ENCISION
AEM® LAPAROSCOPIC INSTRUMENTS

510(k) Summary

JAN 10 2013

Device	**EM3 AEM® Monitor**	
Owner	Encision, Inc. 6797 Winchester Circle Boulder, CO 80301 Phone: (303) 444-2600 Fax: (303) 444-2693	
Contact	James W Lewis VP RAQA	
Date of Summary	4 January 2013	
Subject Device	*Trade name*	EM3 AEM Monitor
	Common name	Electrosurgical, Cutting & Coagulation & Accessories
	Classification	(21 CFR 878.4400, Class II, Product Code: GEI)
Predicate Device	*Trade Names*	EM2 AEM Monitor
	Market Clearance	510(k): K093622 (2010)
	Common name	Electrosurgical, Cutting & Coagulation & Accessories
	Classification	(21 CFR 878.4400, Class II, Product Code: GEI)

Device Description

The EM3 AEM Monitor is the "nerve center" and interface to the electrosurgical generator and instruments for AEM monitoring, a safety system for minimally-invasive electrosurgery.

- For monopolar electrosurgery, AEM technology prevents unanticipated or undetected burns from stray energy along the instrument outside the surgeon's field of view
- In bipolar electrosurgery, the EM3 displays the measurement of high-frequency current flowing through the instrument and tissue as an aid in determining the end-point of bipolar desiccation

The EM3 AEM Monitor system comprises two components

- The Monitor or electronic unit
- A specific or standard ESU Adapter

An ESU Adapter is an accessory to the Monitor containing cords and connectors, which connect the Monitor to the electrosurgical generator (ESU). Multiple models of ESU Adapters are required due to the wide variety of electrosurgical generators in the marketplace and in use in the hospitals.

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Technological Characteristics

The AEM monitor performs different functions for the two types of electrosurgery.

Monopolar electrosurgery	• Monitor connections shunt stray energy, attempting to pass through the insulated shaft of an AEM instrument by insulation breakdown or capacitive coupling, back to the ESU • Monitor shuts down the electrosurgical procedure if the level of stray energy reaches dangerous levels
Bipolar electrosurgery	• Monitor displays the level of flow of electrosurgical current in real-time. (This information aids surgeons in determining the end point of bipolar desiccation.)

The EM3 AEM Monitor is the third generation of AEM monitor; updating, simplifying and improving the features of the second-generation monitor, the EM2, while serving identical indications and uses.

Update	• Electronics/logic system modernized: circuits redesigned using identical analog elements/components while updating firmware to FPGA (field programmable gate array) logic • Alarm visuals—Visual alarms amber in color, per international standard • ESU adapter designs—Redesigned monopolar and bipolar adapters • ESU compatibility—Designed to accommodate new-generation ESU
Simplify	• Connections for hand-control instruments incorporated into monitor • Monopolar ESU adapters with fewer connections and wires
Improve	• Power-interruption response time by interrupting energy delivery directly rather than relying on ESU patient-electrode circuitry • Power measurement accuracy across the spectrum of possible electrosurgical waveforms with increased logic capacity of FPGA • Logic maintenance and support flexibility • Alarm discernment by presenting active-electrode-related alarms (monitor alarms) independent of return-electrode alarms (ESU alarm)

Intended Use

The EM3 AEM Monitor 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 EM3 AEM Monitor performs 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.

Equivalence:

Based on operating principle, intended use, technology, safety, and performance; the EM3 AEM Monitor is substantially equivalent to its predicate device, the EM2 AEM Monitor.

	EM3 AEM Monitor	**EM2 AEM Monitor**
Intended Use	Identical to EM2	Monopolar active-electrode stray-energy shunting and monitoring and bipolar desiccation end point monitoring
Operating principle	• Monopolar high frequency current shunting, measuring, threshold detection, and alarming • Bipolar high frequency ammeter measuring and indicating current • Direct interruption of electrosurgical current to active electrode under fault condition	• Monopolar high frequency current shunting, measuring, threshold detection, and alarming • Bipolar high frequency ammeter measuring and indicating current • Interruption of electrosurgical current under fault condition by tripping ESU contact quality monitor alarm
Materials	Same as EM2	Typical electronic wires, connectors, analog and logic components, circuit boards, and enclosures
Energy source	Identical to EM2	Mains power
Technology	• FPGA logic device • Analog electronics • HF power relays	• Discrete logic components • PAL logic device • Analog electronics • Logic-level relay
Sterilization	None	None
Performance	• Shield circuit to ESU return potential impedance: < 55 pF • Alarm threshold current: 400 mA • Alarm response time ▫ Visual/audible indication from monitor: < 150 ms ▫ Power delivery cessation: < 150 ms • Singular active fault indication from monitor • Current graph granularity: ~120 mA	• Shield circuit to ESU return potential impedance: < 55 pF • Alarm threshold power: 350 mA • Alarm response time ▫ Visual/audible indication from monitor: < 150 ms ▫ Power delivery cessation: > 300 ms (dependent on ESU circuit) • Simultaneous active and return faults alarmed: active on EM2, return on ESU • Current graph granularity: ~30 mA

	EM3 AEM Monitor	EM2 AEM Monitor
EMC and Electrical Safety	• Internal design control assurances • IEC 60601-1 (3rd ed) compliant • IEC 60601-1-2 compliance • IEC 60601-2-2 compliance	• Internal design control assurances • IEC 60601-1 (2nd ed) compliant • IEC 60601-1-2 compliance • IEC 60601-2-2 compliance

Bench Tests:

Complete verification and validation tests were performed in accordance with Design Control requirements per 21 CFR 820.30 for all essential specifications demonstrating substantial equivalence of the EM3 AEM Monitor to the predicate system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Encision, Inc.
% Jim Lewis
6797 Winchester Cir.
Boulder, CO 80301 US

Letter dated: January 10, 2013

Re: K122383
Trade Name: EM3 AEM Monitor AEM Connectors
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 14, 2012
Received: December 17, 2012

Dear Mr. Lewis:

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

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

Enclosure

510(k) Number (if known): **K122383**

Device Name: EM3 AEM Monitor

Indications for Use:

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Prescription Use ✓ (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Brian D. Pullin -S

Division of Surgical Devices
510(k) Number: K122383