

510(k) Summary

K073616

JUL 23 2008

General Information:

Submitter: ELECTROMEDICS Co. LTD.
55 Anderson Avenue
Moonachie, NJ 07074

Contact Person: John Scholz
Tel : 201-935-0770
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Summary Date of Preparation: December 1, 2007

Names:

Proprietary Name: FAS-CLEAN Electrosurgical Coated Active Blade
Common Name: Electrosurgical Electrode
Classification Name: Electrosurgical cutting and coagulation device and accessories

Predicate Devices:

Unimed Coated Blade Electrode (K962935)
Valley Lab's EDGE (K962044)
ConMed's UltraClean (K052104)
Megadyne's EX Clean (K943055)

ELECTROMEDICS' FAS-CLEAN Electrosurgical Coated Active Blade is substantially equivalent to the Unimed Coated Blade Electrode, Valley Lab EDGE, ConMed's Ultra Clean and Megadyne's EZ Clean electrode. The FAS-CLEAN Electrosurgical Coated Active Blade shares the same intended uses, indications for use and the same or similar characteristics including: single use, non-stick properties, sterilization method, and various configurations.,

Device Description

ELECTROMEDICS' FAS-CLEAN Electrosurgical Coated Active Blade is a sterile, single use, coated stainless steel blade. The main parts of the device are the Emralon coated stainless steel blade and the insulated polyethylene sleeve.

Intended Use

The FAS-CLEAN Electrosurgical Coated Active Blade is intended for use by surgeons as an alternative to uncoated stainless steel blades or "non-stick" coated electrodes where monopolar electrosurgical cutting and coagulation blades are normally used.

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Technological Characteristics

The FAS-CLEAN Electrosurgical Coated Active Blade is substantially equivalent in materials and operation to the predicate devices on the market. This device has been designed to comply with the Sterilization of health care products – Requirements for validation and routine control- radiation Sterilization, ISO 11137 and Biocompatibility ISO 10993. There are no new technological characteristics and therefore no new questions of safety and effectiveness.

Performance Data:

No performance data is required for this Class II device nor requested by the Food and Drug Administration (Office of Device Evaluation). A database search has been conducted to evaluate any adverse effects of the device that is currently marketed.

No data submitted for section 807.92 6[(b)(1)(2)(3c)]. See attached documentation of adverse effects.

Conclusion:

The FAS-CLEAN Electrosurgical Coated Active Blade is substantially equivalent to Unimed's Coated Blade Electrode, Valley Lab's EDGE, ConMed's Ultra Clean and Megadyne's EZ Clean Electrodes. The FAS-CLEAN Electrosurgical Active Coated Blade shares the same intended use, indications for use and same or similar technological characteristics as the predicate electrosurgical electrodes.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 23 2008

Electromedics Co., Ltd.
% Mr. John Scholz
55 Anderson Avenue
Moonachie, New Jersey 07074

Re: K073616

Trade/Device Name: FAS-CLEAN Electrosurgical Coated Active Blade
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: April 10, 2008
Received: April 11, 2008

Dear Mr. Scholz:

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 such 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); 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.

Page 2 – Mr. John Scholz

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) K073616

Device Name: FAS-CLEAN Electrosurgical Coated Active Blade

Indications for Use:

The FAS-CLEAN Electrosurgical Coated Active Blade, a single use, sterile, monopolar, Emralon coated electrode is intended for use:

- In surgical procedures (general, neurosurgical, laparoscopic, orthopedic, and gynecologic) where monopolar electrosurgical cutting and coagulation are normally used.
- As an alternative to uncoated stainless steel electrodes or "non-stick" coated electrodes, which are used for these indications.

Prescription Use X
(Part 21 CFR 801 Subpart D)

And/Or Over- The-Counter Use No
(21 CFR 801 Subpart C)



(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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