MAY 2 3 2005

MACAN
ENGINEERING
Electro Surgical Products

1564 North Damen Avenue, Chicago, IL 60622

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No. A9969
ISO 9001-2000
EN ISO 9001-2000
BS EN ISO 9001-2000

## 510 (k) Summary

**K050735**

| | |
|---|---|
| 510 (k) Owner: | David Fried ( address as above ) Board Chairman |
| Contact Person: | Rich Garrett ( address as above ) Product Engineer<br>Mickey Albergo ( Address as above ) Business Manager |
| Preparation Date: | 21 April 2005 |
| Device Classification Name: | Unit, Electrosurgical, and Accessories, Dental |
| Device Proprietary Trade Name: | Radiosurge MC6A |
| Regulation: | 872.4920 |
| Product Code: | EKZ |
| Classification: | Class II |
| Owner/Operator: | MACAN Engineering and Manufacturing Co. |
| Owner/Operator Number | 1418975 |

### Device Description

The Radiosurge MC6A device is an AC-powered device consisting of a controlled power source and a set of cutting and coagulating electrodes. The device is intended to cut or remove soft tissue or to control bleeding during surgical procedures in the oral cavity. An electrical current passes through the tip of the electrode into the tissue and, depending upon the operating mode selected, either cuts through soft tissue or coagulates the tissue.

| Predicate Substantially Equivalent Devices | |
|---|---|
| K955176 | K950239 |
| Ellman Int'l | Parkell |
| Dento-surge 90FFP | Sensimatic 500SE |
| 872.4920 | 872.4920 |
| EKZ | EKZ |
| Class II | Class II |

Summary conclusion: it is reasonable to conclude that the Radiosurge MC6A device is substantially equivalent to the predicate substantially equivalent listed devices in current distribution in terms of clinical indication, generator electrical characteristics and observed histological effect. It is also reasonable to conclude that the submitted device is substantially equivalent to the cited predicate devices in terms of hand piece, dispersive plate, cables, and electrode tips in form, function, electrical parameters, and material including biocompatibility of related engineering thermoplastics and insulation materials.

The summary conclusion is based on the following comparisons:

Comparison of the clinical indications given for the Radiosurge MC6A device and the published clinical indications for the predicate Dento-surge device and the predicate Sensimatic 500SE device by examining available published literature.

Comparison of the Radiosurge MC6A device generator function and the predicate Dento-surge device was done on the basis of published specification, laboratory measurements conducted at Macan using a production sample of the Dento-surge device, examination of comparative histological effects in a biologic test medium, and anecdotal clinical comparisons of the Radiosurge device and the predicate device. The Sensimatic 500SE device was not compared for generator function.

Comparison of the physical science related to the respective devices was conducted by reference to relevant scientific literature.

Comparison of the respective device hand pieces was conducted by physical examination and electrical measurements for form and function. While substantially equivalent in those respects, it should be noted that while these accessories differ materially, both respective materials each have manufacturer bio-compatibility data available. The Radiosurge device accessory hand piece employs polysulfone material, trade name AMOCO Udel P-1700 #937 ( black ) for which the manufacturer cites FDA 21 CFR 177.1655 and UL E36098 compliance. Thee Sensimatic 500SE was not compared for the hand piece accessory.

Comparison of the respective device dispersive plates was made by physical examination and electrical measurements conducted on a production sample of the predicate Dento-surge device, by examining histological effects in a test media, and by means of the anecdotal clinical comparisons cited. It should be noted that the respective dispersive plates differ in size but provide substantially equivalent clinical function. The Sensimatic 500SE device was not compared for dispersive plate function, except to note that said accessory is dimensionally similar to the Dento-surge device.

Comparison of the respective device accessory electrode tips was made on the basis of equivalence in form, function, clinical application, and material as published by the predicate Dento-surge device manufacturer in terms of interchangeable part numbers ( Ellman Radiosurgery catalog, copyright 1990 ). The colors of the respective insulation materials differ leading to the question of dye bio-compatibility. The Sensimatic 500SE accessory electrodes are materially equivalent to the Radiosurge accessory electrodes and are the same color, hence, it is reasonable to conclude on the basis of existing approvals that the Radiosurge accessory electrodes are substantially equivalent to listed predicate devices on the basis of form, function, intended clinical application, and biocompatibility.

The Radiosurge device has been examined by UL and complies with standard UL 60601 as tested to IEC 60601-1-1, IEC 60601-1-2, and IEC 60601-2-2 as an isolated output monopolar electrosurgical generator, and is listed under number 6UA7 bearing the C/US mark. The Dento-surge device was UL listed to standard UL544 under number 483E. The Sensimatic 500SE device is CE marked as compliant with IEC 60601-1-1 and IEC 60601-1-2, but not IEC 60601-2-2. It is felt that these differences do not represent any disparity in compared clinical application, generator therapeutic electrical currents, or the intended histological effects derived there from.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 3 2005

Mr. Rich Garrett
Product Engineer
Macan Engineering Company
1564 North Damen Avenue
Chicago, Illinois 60622

Re: K050735
Trade/Device Name: Radiosurge MC6A
Regulation Number: 872.4920
Regulation Name: Dental Electrosurgical Unit and Accessories
Regulatory Class: II
Product Code: EKZ
Dated: May 11, 2005
Received: May 13, 2005

Dear Mr. Garrett:

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.

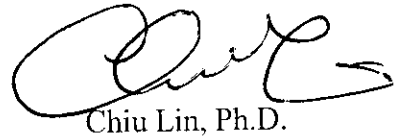
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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.

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050735

# Indications for Use

510(k) Number (if known): K050735

Device Name: Radiosurge MC6A

Indications For Use:

Soft tissue management within the oral cavity to address the indications for incision, excision and coagulation to induce hemostasis in intra-oral soft tissue.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices



510(k) Number: K050735