K083569

CONFIDENTIAL

510(K) SUMMARY

APR - 1 2009

This Summary of Safety and Effectiveness is in accordance with the requirements of:

- Device Description

SURGYBONE, the electromedical equipment by SILFRADENT Srl, is a dental instrument performing operations in the field of dental prosthesis and endodontics by means of ultrasound vibrations produced by a piezoelectric transducer.

The equipment consists of a console including an electronic control circuit and an ultrasound control circuit, a piezoelectric handpiece and a peristaltic pump. Suitable tips are mounted to the piezoelectric handpiece.

The system is based on a sophisticated ultrasound control structure, which by means of current measurement, carries out electrical resonance handpiece control. All operations are displayed and controlled by a card through a monitor and a keyboard. The integrated pump is used to transport the sterile coolant from its vessel to the preparation point.

The Surgybone

- Intended use

SURGYBONE, the electromedical equipment by SILFRADENT Srl, is a dental instrument performing operations in the field of oral surgery, by means of ultrasound vibrations produced by a piezoelectric transducer.

- Summary of Substantial Equivalence Discussion

K080220 UBS&UDD manufactured by ITALIA MEDICA s.r.l.

K060274 PIEZOTOME manufactured by SATELEC

K043408 PIEZOSURGERY manufactured by PIEZOSURGERY, INC. (distributed in USA by MECTRON s.p.a.)

The proposed and predicated devices use similar components and are similar in design, technical characteristics and mode of operation. The proposed and the predicated devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Silfradent S.R.L.
C/O Ms. Claude Berthoin
President
Denterprise International, Incorporated
110 East Granada Boulevard, Suite 208
Ormond Beach, Florida 32176

APR - 1 2009

Re: K083569
Trade/Device Name: SURGYBONE
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: II
Product Code: DZI
Dated: March 25, 2009
Received: March 26, 2009

Dear Ms. Berthoin:

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.

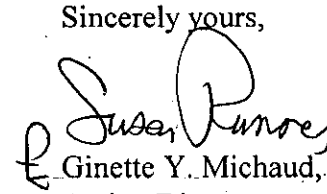
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

Applicant: SILFRADENT s.r.l.

510(k) Number (if known): K083569

Device Name: SURGYBONE

Indication For Use:
This device is a dental bone cutting instrument performing operations in the field of oral surgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE).

Susan Runner

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

510(k) Number: K083569