FEB 1 2006

K053178

510(k) SUMMARY

Submitter

Keith Dunn
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Date Prepared 11/01/05

Device Name

Trade name	Symmetry S-Series Piezo Scaling Tips
Common name	Dental Ultrasonic Scaler
Classification name	Ultrasonic Scaler

Legally marketed Devices to which equivalence is claimed:

Satelec Suprasson P-Max	K942139
Satelec Suprasson P5 Booster	K961158

Description of the device
The Hu-Friedy® brand Symmetry S-Series Piezo Scaling Tip is similar to the Piezo Scaling Tips used with the predicate devices listed above.

This device is intended to be used by dental professionals for dental cleaning and periodontal therapy to remove calculus from the teeth.

The Symmetry S-Series ultrasonic insert has essentially the same design as the predicate device's ultrasonic inserts. Laboratory tests performed to make this determination include cleaning, sterilization, and mechanical life testing. The key elements of piezoelectric ultrasonic tip compatibility include: correspondence of tip thread to hand-piece specification, tip vibration at resonant frequency established by equipment specification

(27-32 kHz) and a linear tip displacement in a range consistent with the power output setting on the generator. At the conclusion of engineering design control testing, it was found that critical elements of design, resonant frequency and tip displacement are compatible with the predicate device's tips.

To determine if the Symmetry S-Series ultrasonic insert performed similar to or better than the predicate device, a field evaluation was undertaken. For the field study, clinicians were asked to evaluate the inserts as related to scaling efficiency, adaptability to the tooth surface, water delivery, patient comfort during use and overall preference. The overall conclusion of this evaluation was that the Symmetry S-Series tips were perceived to be equal to, or slightly better than the predicate device's competitive tip.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 2006

Mr. Keith Dunn
Regulatory Affairs
Hu-Friedy Manufacturing Company, Incorporated
3232 North Rockwell Street
Chicago, Illinois 60618

Re: K053178
Trade/Device Name: Symmetry S-Series Piezoelectric Scaling Tips
Regulation Number: 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: October 17, 2005
Received: November 17, 2005

Dear Mr. Dunn:

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

K053178

Indications for Use

510(k) Number (if known): _____

Device Name: Symmetry S-Series Piezoelectric Scaling Tips

Indications for Use:
To be used by Dental Professionals during dental cleaning and periodontal (gum) therapy to remove calculus, plaque and staining of the teeth by application of an ultrasonic vibrating tip to the teeth.

Prescription Use ✓ 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)

Concurrence of CDRH, Office of Device Evaluation

Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

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