K130137

COLTENE®

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Cuyahoga Falls, OH 44223
Unites States of America
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"510(K) SUMMARY" AS REQUIRED BY SECTION 807.92(c)
Modified July 15, 2013

510(k) Owner's Name, Address, Telephone Number, Fax Number, Contact Person and Date Prepared.

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AUG 2 3 2013

Contact Person:

Edward A. Kroll
President, Spectre Solutions, Inc. and
Representative Consultant for
Spinergy, Inc.
5905 Fawn Lane
Cleveland, Ohio 44141
Phone: (440) 546-9810
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Date Prepared: July 15, 2013

Name of Device

- Trade Name: BioSonic Suvi Piezoelectric Scaler and Polisher
- Common Name: Scaler
- Classification Name:
  - Scaler, Ultrasonic

Predicate Device

EMS Electro Medical Systems EMS Air-Flow Master Piezon (K110173)

Device Description:

The BioSonic Suvi Piezoelectric Scaler and Air Polisher (BioSonic Suvi) is a combination scaler and polisher device for use in dental care. It combines the functions of an ultrasonic scaler and dental air polisher into a single device.

The scaler is used for removal of tartar or calculus on teeth and other dental work where ultrasonic vibration is beneficial. The polisher unit is used for removal of plaque, cleaning discolored teeth and other dental work where air polishing is beneficial.

The BioSonic Suvi will be offered in (4) four different models. These are the BioSonic Suvi Premier, BioSonic Suvi Premier Plus, BioSonic Suvi Elite and the BioSonic Suvi Elite Plus. The Premier and Premier Plus are scalers only. The Elite and Elite Plus are combination scaler and polisher units

The Premier and Plus versions differ in whether they include a standard tap water supply attachment or an optional medicament dispenser system. The standard tap water versions connect directly to a tap water supply using a hose connection. The medicament dispenser system provides either medicine or clean water using a medicament bottle which connects to the side of the unit.

The medicament versions utilize an internal air compressor to pressurize the medicament. During use, compressed air forces fluids from the bottle, through the hose, to the hand piece and the tip/nozzle. Thus medication can be provided if desired.

Device Function

Scaler:

The scaler includes a power unit and ultrasonic hand piece with scaler tip. A mechanical resonator within the scaler tip vibrates when power is supplied to the hand piece. When held against the tooth, sound waves bounce off the tooth and cause the tartar and plaque to break up. Water coming from the scaler then washes away the broken debris.

Polisher:

The polisher includes a power unit, a water line, an air/powder line and a hand piece nozzle. It functions by spraying pressurized water mixed with a polishing agent onto the surface of the teeth. This mixture washes away residue and plaque while removing stains and neutralizing acidic conditions in the mouth.

Scientific Concepts

Scaler:

The scaler utilizes the scientific concept of piezoelectricity whereby materials, such as piezoelectric crystals, have the ability to generate a voltage when a mechanical force is applied to them. The scaler hand piece contains a mechanical resonator that is coupled to the scaler tip. The resonator is driven by a power electronic unit.

The conversion of the electrical signal to mechanical movement is achieved by a piezoelectric ceramic plate within the hand piece. The resulting movement of the ceramic plate is transferred to a metal resonator which is brought into resonance by selecting the correct frequency. This movement is transferred to the scaler tip causing the outer part of the tip to vibrate.

Polisher:

The polisher incorporates the basic principle of using pressurized air, mixed with water and a polishing agent as a method of cleaning and polishing. This mixture removes extrinsic stains, dental plaque and soft debris while simultaneously polishing tooth surfaces.

Significant Physical and Performance Characteristics

Design:

- Portable stand-alone device
- Combination scaler and polisher in one unit
- Equipped with LED lights that provide for optimal visibility
- Equipped with either a tap water connector or quick-connect water/medicament dispenser.

Materials:

Component	Material
LED lens	Polysulfone
Scaler tips and air polisher nozzle	Stainless steel
Handpiece Grip	Silicone
Housing and top of housing	ABS
Handpiece (external)	PEEK
Water line tubing	Polyurethane
Air line tubing	Polyurethane

Physical Properties:

Item	Elite	Elite Plus	Premier	Premier Plus
***Dimensions**	270 x 140 x 165 mm	270 x 140 x 165mm	270 x 140 x 165 mm	270 x 140 x 165 mm
Weight	3400 g	3400 g	2900 g	2900 g
Voltage	100, 115, 230 Vac, 50-60 Hz	Same	Same	Same

*Without bottle and powder container attachments

Intended Use/Indications for Use

The BioSonic Suvi ultrasonic scaler is intended for use in dental applications such as supra and subgingival scaling, periodontal therapy, endodontic procedures and cavity preparation.

The BioSonic Suvi Air Polisher is intended for use in the cleaning, surface preparation and polishing of teeth by the projection of water, air and dental powders onto the tooth surface. The device removes dental plaque, soft deposits, and surface stains from pits, grooves, interproximal

spaces or smooth surfaces of teeth. The BioSonic Suvi Air Polisher is also indicated for the non-surgical removal of subgingival plaque in pockets up to 5 mm after initial periodontal treatment.

Predicate Device Comparison

The BioSonic Suvi Piezoelectric Scaler and Polisher (BioSonic Suvi) is substantially equivalent to the EMS Electro Medical Systems SA EMS Air Flow Master Piezon (EMS Air Flow) Ultrasonic Scaler and Polisher Unit. This device was granted marketing clearance by FDA on April 7, 2011 under 510(k) Accession Number K110173.

Both of these products are electrically powered, electromechanical devices designed for use in dental applications. They are constructed from the same basic materials, incorporate the same operational principles and both use AC power as their power source. Additionally, both devices include a footswitch, an Ultrasonic Scaler and a Polisher.

Both devices are intended for use in the cleaning and polishing of teeth by the projection of water, air, and dental powders onto the tooth surface. Additionally, both devices remove dental plaque, soft deposits, and surface stains from pits, grooves, interproximal spaces, or smooth surfaces of teeth. Finally, both can be used for a variety of dental applications.

Performance Data: (Non-clinical Testing)

The BioSonic Suvi Piezoelectric Scaler and Polisher has been tested to and meets the requirements of;

- IEC 60601-1/EN 60601-1 Medical electrical equipment, Part 1: General requirements for basic safety and essential performance
- EN 60601-1-2 Medical electrical equipment, Parts 1-2 : General requirements for safety-Collateral standard: Electromagnetic compatibility – Requirements and tests

Conclusion:

The BioSonic Suvi Piezoelectric Scaler and Polisher is substantially equivalent to its predicate device. It has the same indications for use, is constructed from the same basic materials and incorporates the same operational principles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

August 23, 2013

Coltene/Whaledent
C/O Mr. Edward Kroll
President
Spectre Solutions, Incorporated
5905 Fawn Lane
CLEVELAND OH 44141

Re: K130137
Trade/Device Name: BioSonic Suvi Piezoelectric Scaler and Polisher
Regulation Number: 21 CFR 872.4850
Regulation Name: Dental Scaler, Dental Polisher
Regulatory Class: II
Product Code: ELC, EFB
Dated: July 22, 2013
Received: July 31, 2013

Dear Mr. Kroll:

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 contact 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): TBD

Device Name: BioSonic Suvi Piezoelectric Scaler and Polisher

Indications For Use:

The BioSonic Suvi ultrasonic scaler is intended for use in dental applications such as supra and subgingival scaling, periodontal therapy, endodontic procedures, cavity preparation, and restorative dentistry.

The BioSonic Suvi Air Polisher is intended for use in the cleaning, surface preparation and polishing of teeth by the projection of water, air and dental powders onto the tooth surface. The device removes dental plaque, soft deposits, and surface stains from pits, grooves, interproximal spaces or smooth surfaces of teeth. The BioSonic Suvi Air Polisher is also indicated for the non-surgical removal of subgingival plaque in pockets up to 5 mm after initial periodontal treatment.

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)

Concurrence of CDRH, Office of Device Evaluation (ODE) Page 1 of 1

Andrew I. Steen -S
2013.08.22 08:53:55 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Respiratory, Infection Control and
Dental Devices
510(k) Number: K130137