Aseptico Inc.
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Woodinville, WA 98072

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www.aseptico.com
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K030163

510(k) Summary

MAR 0 3 2003

Contact: Grant Ramaley

Date Prepared: September 16, 2002

Trade or Proprietary Name: Aseptico VCT Versatile Control Technology Model AEU-925

Classification Name: 872.4200 Dental Handpiece and Accessories

Description of characteristics

This programmable dental system digitally controls the speed, direction and torque of a low voltage dental motor. Each dental system has programmed into memory a library of speed and torque settings for commonly used Endodontic files and dental implants. The AEU-925 can also be programmed by the dentist to hold in memory six speed and torque settings that they prefer to use most. The speed and torque limiting features are intended to reduce over-tightening of Endodontic files and dental implants.

List of features:

1) Stores speed and torque settings in its "Library" that can be recalled later

2) Allows the operator to select the "mode" of operation from either "Implant" or "Endodontic" operation.

3) Has a built in dynamometer to calibrate the handpiece, motor and console prior to use.

4) Uses the autoclavable motor AE-9A-30.

5) Has a built in water pump to provide irrigation

6) Allows connectivity to a personal computer to upload new settings,

7) Foot control AE-19 can be used to activate water on/off, change forward/reverse direction of the drill, scroll through various presets that are in the program menu,

8) Allows the operator to use voice commands to step through library of preset speed and torque values.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 3 2003

Aseptico, Incorporated
C/O Mr. Charles Mack
Responsible Third Party Official
Underwriters Laboratories, Incorporated
2600 N. W. Lake Road
Camas, Washington 98601-8542

Re: K030163
Trade/Device Name: Aseptico's AEU-925 VCT Versatile Command Technology
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EKX
Dated: February 13, 2003
Received: February 21, 203

Dear Mr. Mack:

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.

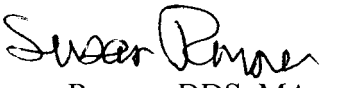
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4613. 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/dsma/dsmamain.html

Sincerely yours,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K030163

Device Name: Dental Handpiece and Accessories

Indications For Use:

Aseptico's AEU-925 VCT can be used for a wide range of dental procedures including;

1) Dental endodontic surgeries, such as drilling into the root canal.

2) General dentistry, such as removing carious material from the dentine.

3) Performing dental implant surgeries, such as perforating the bone, and tapping and threading procedures required before placement of implant prosthetics.

(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: K030163

Prescription Use ✓ OR Over-The-Countern Use_____
(Per CFR 801.109)

(Optional Format 1-2-96)