K111078

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DEPT OF QUALITY AND REGULATORY AFFAIRS

510(k) Summary

Prepared by: Grant Ramaley **March 16, 2011**

Device Description

Model Number: AEU-26L

Classification Name: 872.4200 Dental handpiece and accessories

Product Code: EKX handpiece, direct drive, ac-powered

Primary accessories exclusive to the AEU-26L system:

a) AEU-26L Consol (Controller)
b) AE-250L-30 Low Voltage Electric Motor
c) On/Off Foot Pedal
d) Motor holder attaching bracket

Intended Use

For use in a wide range of dental procedures including; endodontic surgeries, such as drilling in to the tooth canal, and general dentistry, such as removing carious material from the dentin.

Summary of Technological Characteristics

General operation and use
The AEU-26L is software controlled and has the following features:

a) Allows adjustment of the motor speed from 300 to 30,000 RPM
b) Allows setting the torque applied to the motor in gram/cm
c) Allows selection of gear ratios for different geared E-Type handpieces
d) Allows selection of forward or reverse drive rotation
e) Allows reciprocating drive (forward/reverse cycling)
f) Allows use of a foot pedal control to operate the attached handpiece motor
g) Allows the user to define their own presets for speed (RPM) and torque (gram
h) Allows for attaching geared handpieces that include optics for a light.

See Table 1 of comparisons provided at the end of this summary

Substantial Equivalence

Feature equivalency to Aseptico Model AEU-925:
All but two of the features listed above "Technological Characteristics" for the AEU-26L are already part of Aseptico's model AEU-925, which was cleared under 510(k) number K030163. Both models can be used for endodontic surgery.

****Allows attachment of lighted handpieces**
The AEU-26L allows use of contra angle handpieces that include optics for a light, to provide illumination from the Light Emitting Diode (LED) of the AE-250L motor. This technology is substantially equivalent to the Aseptic AEU-5000 cleared under 510(k) number K103399.

****Reciprocating drive**
Reciprocating drive is a forward and reverse cycle that can be selected as an alternate motion to simply driving forward or reverse. Bench testing of the AEU-26L establishes that the AEU-26L provides the same type of reciprocation as the ATR TECNIKA device, cleared under K000547.

****Technological characteristics from predicate devices other than Aseptico's Model AEU-925**

Performance data

The AEU-26L was assessed to IEC 60601-1:1988—Medical electrical equipment—Part 1: General requirements for safety. This included thermal and electrical safety of the AE-250L-30 motor containing the Light Emitting Diode (LED).

The AEU-26L met electromagnetic compatibility requirements of IEC 60601-1-2—Medical electrical equipment—Part 1: General requirements for safety—2. Collateral standard: Electromagnetic compatibility.

Specific performance testing relevant to the AE-250L-30 motor is met by application of ISO 11498 Dental handpieces -- Dental low-voltage electrical motors

All of the functional characteristics for the AEU-26L (e.g. directional and reciprocating drive, speed, torque control, ability to attached selected geared handpieces, etc) were established using comparative design verification methods between the predicate devices and the AEU-26L. Records of these design verification activities are maintained in the Design History File.

Conclusions

The AEU-26L bears all the features necessary to perform endodontic surgery of its predecessor AEU-925, using all of the same technological developments and feature that are in place for performing endodontic dental surgery. In addition, the AEU-26L includes the ability to utilize legally marketed geared handpieces that have optics to carry the light for illuminating the working area of the tooth. It also includes a reciprocating drive feature that is substantially equivalent to the ATR TECNIKA device, cleared under K000547.

TABLE 1

SUMMARY ONLY -- See Substantial Equivalence Discussion for more details

Comparison chart of AEU-26L Essential Performance and Features

	AEU-26L	AEU-925	ATR TECNIKA	AEU-5000
a) Allows adjustment of the motor speed from 300 to 30,000 RPM	300 to 30000 RPM Configurable	300 to 30000 RPM Configurable	1600 to 12800 RPM Configurable	2000 to 40000 RPM Configurable
b) Allows setting the torque applied to the motor in gram/cm	*Yes Better than predicate device AE- 925 Torque accuracy	*Yes Torque accuracy	Units not in gram/cm. Torque is configurable from 0 to 100 (no units specified)	Units not in gram/cm. Torque is configurable from 5% to 100%
c) Allows selection of gear ratios for different geared E-Type handpieces	1:5, 1:1 8:1, 16:1 Reduction	1:5, 1:4, 1:3, 1:2, 1:1 35:1 to 3:1 Reduction	1:1 8:1, 16:1, 18:1, 20:1 Reduction	1:5, 1:2, 1:1 5:1 and 8:1 Reduction
d) Allows selection of forward or reverse drive rotation	Yes	Yes	Yes	Yes
e) Allows reciprocating drive (forward/reverse cycling)	Yes	No	Yes	No
f) Allows use of a foot pedal control to operate the attached handpiece motor	Yes, electronic foot control	Yes, electronic foot control	Yes, electronic foot control	Yes, pneumatic sensor
g) Allows the user to define their own presets for speed and torque	Yes	Yes	Yes	Yes
h) Allows for attaching geared handpieces that include optics for a light.	Yes	No	No	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Aseptico, Incorporated
C/O Mr. Jeff D. Rongero
Responsible Third Party Official
Underwriters Laboratories, Incorporated
12 Laboratory Drive
Research Triangle, North Carolina 27709

JUN 14 2011

Re: K111078
Trade/Device Name: AEU-26L
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: II
Product Code: EKX
Dated: June 7, 2011
Received: June 8, 2011

Dear Mr. Rongero:

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.

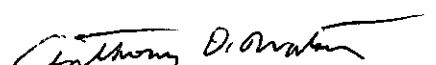
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: AEU-26L

Indications For Use:

For use in a wide range of dental procedures including; endodontic surgeries, such as drilling in to the tooth canal, and general dentistry, such as removing carious material from the dentin.

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)

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

510(k) Number: k111078