K030895

DEC - 3 2003

Aseptico Inc.
8333 216th Street SE
Woodinville, Washington 98072
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510(k) Summary

Contact: Grant Ramaley

Date Prepared: March 17, 2003

Trade of Proprietary Name: Aseptico Endopex V Model Number AEU-40

Classification Name: Unclassified

Product Code: LQY - Locator, Root Apex

Endopex V operating principals

Using two electrodes, electrical impedance is measured between a root canal file positioned inside the tooth and another making contact with the oral cavity along the lip.

The software inside the Endopex V compares the impedance values being read between its two electrodes with impedance values stored in its software database. The comparison of impedance values are than converted to readings on the LED to indicate the estimated position of the endodontic file in relation to the inside root canal and the Apical Foramen.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 3 2003

Mr. Grant Ramaley
Quality and Regulatory Affairs Manager
Aseptico Incorporated
8333 216th Street SE
Woodinville, Washington 98072

Re: K030895
Trade/Device Name: Endopex V Model AEU-40
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LQY
Dated: February 3, 2003
Received: September 4, 2003

Dear Mr. Ramaley:

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.

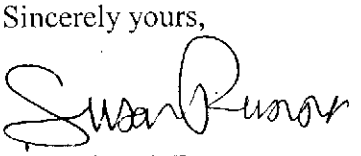
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



for 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

510(k) Number (if known): K030895

Device Name: ***ENDOPEX V Model AEU-40***

Indications For Use:

The Endopex V is used to estimate the position an endodontic file in the root canal. The devices enhances endodontic surgery by enabling the dentist to reduce the number of required radiographs.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Robert S Betz DDS for Dr Susan Runner

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

510(k) Number: K030895