MAY 27 2003

K030884

Abbreviated 510 (k) Summary

Acadental

Name & Address **Acadental**
5830 Woodson St.
Suite 5
Mission, KS. 66202
(913) 384-7390
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CONTACT: Christopher Craig

DATE PREPARED: March 7, 2003

TRADE OR PROPRIETARY NAME: Aptus Blue

CLASSIFICATION NAME: Dental Instrument 872.4565 Class I device

PREDICATE DEVICE: RCT Gel K972234
RC Prep Pre-1976 device

DEVICE DESCRIPTION: Aptus Blue is a 3cc endodontic syringe containing EDTA solution. Aptus Blue allows for cleansing action that facilitates easy removal of vital pulp tissue and necrotic tissue from the root canal. It is designed to be used with endodontic irrigation solutions and sodium hypochlorite solutions.

INTENDED USE: Aptus Blue is used in the cleansing of the root canal preparation during endodontic therapy.

TECHNOLOGICAL CHARACTERISTICS: All components in Aptus Blue have been used in predicate medical devices or have been found safe for dental use.

We believe that, due to the long established safe and effective use of the predicate device and the identical concentrations of active ingredients, limited contact time within the oral cavity, decomposition, and thorough removal of the product from the canal space, the use of Aptus Blue does not require additional biocompatibility testing and that the device is safe and effective for the intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2003

Mr. Christopher Craig
Sales Manager
Acadental
5830 Woodson, Suite 5
Mission, Kansas 66202

Re: K030884
Trade/Device Name: Aptus Blue®
Regulation Number: N/A
Regulation Name: Root Canal Cleanser
Regulatory Class: Unclassified
Product Code: KJJ
Dated: March 07, 2003
Received: March 20, 2003

Dear Mr. Craig:

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. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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

INDICATION OF USE STATEMENT

510(K) Number (IF KNOWN): K030884

DEVICE NAME: Aptus Blue

INDICATION FOR USE:

Aptus Blue is used in the cleansing of the root canal preparation during endodontic therapy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **Or** **Over-The-Counter-Use** _____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**

Kevin Mulley for MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030884

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