2/25/1999

K990225

SYBRON DENTAL SPECIALTIES

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
(714) 516-7484 - Phone
(714) 516-7488 - Facsimile
Colleen Boswell - Contact Person

Date Summary Prepared: January 1999

Device Name:

- Trade Name - Endo Analyzer, Model 8005, Modified
- Common Name - Endodontic Analyzer
- Classification Name - Pulp Tester, per 21 CFR § 872.1720

Devices for Which Substantial Equivalence is Claimed:

- Analytic Endodontics, *Endo Analyzer, Model 8005*

Device Description:

The device is a battery-operated, endodontic analyzer which is designed to test the vitality of a tooth (by passing a pulsed, low-current, varying-voltage signal through the tooth) and to locate the apical foramen of a root canal (by measuring the impedance within a root canal) during root canal treatment. The unit is battery operated using six (6) 1.5 volt size AA alkaline batteries. An automatic power-off feature saves battery life and assures that the device is not left on inadvertently. The unit may be used in either of two modes, V.S. as a pulp tester or A.F. as an apex locator. The endodontic analyzer is controlled by a microprocessor and the handpiece and cord assembly are completely removable. The probes, lip clips and file clips used with the device are autoclavable.

Intended Use of the Device:

The intended use of the endodontic analyzer is to test the vitality of a tooth and to locate the apical foramen of a root canal in conjunction with endodontic root canal treatment.

Substantial Equivalence:

The endodontic analyzer is substantially equivalent to several other legally marketed devices in the United States. The modified design of the Endo Analyzer, Model 8005, functions in a manner similar to and is intended for the same use as the original Endo Analyzer, Model 8005 designed by Analytic Endodontics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 25 1999

Ms. Colleen Boswell
Senior Regulatory Affairs Specialist
Sybron Dental Specialties, Incorporated
1717 W. Collins Avenue
Orange, California 92867

Re: K990225
Trade Name: Endo Analyzer, Model 8005, Modified
Regulatory Class: II
Product Code: EAT
Dated: January 21, 1999
Received: January 25, 1999

Dear Ms. Boswell:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K990225

Device Name: ENDO ANALYZER, MODEL 8005, MODIFIED

Indications For Use:

510(k) Number: _____

Device Name: Endo Analyzer, Model 8005, Modified

Indications for Use:

The Endo Analyzer, Model 8005, Modified is intended to be used in dentistry to test the vitality of a tooth and to locate the apical foramen of a root canal in conjunction with endodontic root canal treatment.

(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 Dental, Infection Control,
and General Hospital Devices
510(k) Number K990225

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)