DEC - 8 1997
K973439

SYBRON
DENTAL SPECIALTIES, INC.

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: September 1997

Device Name:

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

Devices for Which Substantial Equivalence is Claimed:

- Analytic Technology Corporation, Apex Finder A.F.A.
- Analytic Technology Corporation, Vitality Scanner

Device Description:

The device is a battery-operated, endodontic analyzer which is designed to test the vitality of a tooth and to locate the apical foramen of a root canal during root canal treatment. The unit is battery operated using three (3) 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 vitality scanner 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 handpiece and cord assembly, including the vitality scanner tips and lip clip 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 Vitality Scanner and Apex Finder A.F.A. marketed by Analytic Technology Corporation function in a manner similar to and are intended for the same use as the product manufactured by Analytic Technology Corporation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 8 1997

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

Re: K973439
Trade Name: Endo Analyzer, Model 8005
Regulatory Class: II
Product Code: EAT
Dated: September 8, 1997
Received: September 10, 1997

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

Section I - Indications for Use

510(k) Number: K973439

Device Name: Endo Analyzer, Model 8005

Indications for Use:

The Endo Analyzer, Model 8005, 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.

(Division Sign-Off) Pamela Scott for Susan Runner
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K973439