JUN 1 9 2002

K021298

SYBRON DENTAL SPECIALTIES

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

Submitter:

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

Date Summary Prepared: April 2002

Device Name:

- Trade Name – *Elements Diagnostic Unit*
- Common Name – Endodontic Diagnostic Unit
- Classification Name – Pulp Tester, per 21 CFR § 872.1720

Devices for Which Substantial Equivalence is Claimed:

- Sybron Endo/Analytic, *Endo Analyzer, Model 8005, Modified*

Device Description:

The device is a battery-operated, endodontic diagnostic unit designed to be used in either of two modes, V as a pulp tester to test the vitality of a tooth (by passing a pulsed, low-current, varying-voltage signal through the tooth), or A as an apex locator to locate the apical foramen of a root canal (by measuring the impedance within a root canal) during root canal treatment. The unit uses a rechargeable battery pack, and can be used while the pack is charging. A remote satellite display that mirrors the values on the unit's graphic display can be attached to a chair, patient's bib or microscope for a more ergonomic monitoring of diagnostic status. To improve visibility and decrease eyestrain, the main body of the unit can be rotated from a vertical orientation to a 30° angle. The automatic power-off feature saves battery life and assures that the device is not left on inadvertently. The endodontic diagnostic unit is controlled by a microprocessor that is designed to support a network style communication allowing information to be shared between endodontic devices. The remote satellite display 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 *Elements Diagnostic Unit* is 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.

Substantial Equivalence:
Elements Diagnostic Unit is substantially equivalent to other legally marketed devices in the United States. *Elements Diagnostic Unit* functions in a manner similar to and is intended for the same use as the *Endo Analyzer, Model 8005, Modified* marketed by Sybron Endo/Analytic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2002

Sybron Endo/Analytic
C/O Ms. Colleen Boswell
Sybron Dental Specialties
1717 West Collins Avenue
Orange, California 92867

Re: K021298
Trade/Device Name: Elements Diagnostic Unit
Regulation Number: 872.1720
Regulation Name: Pulp Tester
Regulatory Class: II
Product Code: EAT
Dated: April 23, 2002
Received: April 24, 2002

Dear Ms. Boswell:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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). 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,

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

Enclosure

K021298

Section I

Indications for Use Statement

Ver/ 3 - 4/24/96

Applicant: Sybron Endo/Analytic

510(k) Number (if known): _____

Device Name: Elements Diagnostic Unit

Indications For Use:

The *Elements Diagnostic Unit* 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.

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021298

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)
(Optional Format 1-2-96)