APR 2 8 2004

K031664

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: May 2003

Device Name:

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

Devices for Which Substantial Equivalence is Claimed:

- Sybron Endo/Analytic, *System B HeatSource*
- Obtura Spartan, *Obtura II*

Device Description:
The device is an AC powered endodontic unit designed to be used in either of two modes, a) the System B Mode to 1) downpack and backfill gutta percha during root canal obturation, 2) test tooth response to thermal stimulus (Hot Pulp Test) and 3) for tissue cautery, and b) the Extruder Mode to backfill gutta percha during root canal obturation. The unit has an LCD screen with membrane switch controls. When using the unit in the System B Mode, the user may select the appropriate switch to downpack, backfill, cauterize or hot pulp test. While the temperature has a preset value with each of the four selections, it can also be adjusted using the temperature adjust button. In the Extruder Mode, the user may select the gutta percha type (alpha or beta), speed of extrusion (high or low), alarm sound setting and volume/mode. The endodontic obturation unit is controlled by a microprocessor that is designed to support a network style communication allowing information to be shared between endodontic devices. The System B and Extrusion hand pieces are completely removable and autoclavable.

Intended Use of the Device:

The intended use of the *Elements Obturation Unit* is to be used in dentistry to provide continuous heat at the tip of a dental instrument to test tooth response to thermal stimulus, for tissue cauterization and coagulation and to backfill and downpack gutta percha during endodontic root canal treatment. Additionally, when the unit is used in the Extruder Mode, the *Elements Obturation Unit* is used to backfill gutta percha during root canal obturation.

Substantial Equivalence:

The *Elements Obturation Unit* is substantially equivalent to other legally marketed devices in the United States. The *Elements Diagnostic Unit* functions in a manner similar to and is intended for the same use as the *System B HeatSource* manufactured by Sybron Endo/Analytic and the *Obtura II* manufactured by Obtura Spartan.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 8 2004

Sybron Dental Specialties, Incorporated
Ms. Colleen Boswell
Director, Corporate Compliance
Division of Ormco Corporation
1717 West Collins Avenue
Orange, California 92867

Re: K031664
Trade/Device Name: Elements Obturation Unit
Regulation Number: 872.4562
Regulation Name: Dental Hand Instrument
Regulatory Class: I
Product Code: EKR
Dated: March 2, 2004
Received: March 3, 2004

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.

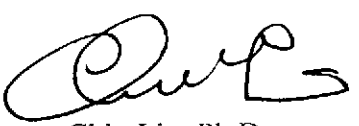
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



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

K031664

Indications for Use

510(k) Number (if known): K031664

Device Name: Elements Obturation Unit

Indications For Use:

The Elements Obturation Unit is intended to be used in Dentistry to:

1. Provide continuous heat at the tip of a dental instrument to test tooth response to thermal stimulus,
2. For tissue cauterization and coagulation, and
3. To backfill and downpack gutta percha during Endodontic root canal treatment.

4. When in Extruder mode, the Elements Obturation Unit is used only to backfill gutta percha during root canal obturation.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MSR

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

510(k) Number: K031664