Submitted by: Young OS LLC  
Obtura Spartan  
1663 Fenton Business Park Ct.  
Fenton, Missouri 63026  
(636) 343-8300  

Contact Person: Stephen W. Conger, Jr.  

Date Prepared: September 22, 2004  

Proprietary Name: Obtura  

Common name: Obtura Heated Gutta Percha System  

Classification Name: Instrument, Filling, Plastic, Dental  

Predicate Device: Heated Gutta Percha System  
510(k) #K832654  
and/or  
Elements Obturation Unit  
510(k) #K031664  

Description of the Device: The device is an electrically powered dental device used for heating gutta percha and placing the softened material into prepared root canals of teeth during root canal therapy. The Obtura is an established device that has been marketed for over 20 years with an estimated 30,000 in use worldwide. This model incorporates interchangeable handpieces, membrane switches, and temperature memory controls. The user gently squeezes the trigger to express the desired amount of gutta percha into the root canal through a soft silver applicator needle as the predicate Heated Gutta Percha System, #K832654.

Intended Use of the Device: The Obtura is intended for use by professionally qualified dentists, endodontists and dental clinicians to heat Gutta Percha and to place it into the previously prepared root canals of human teeth, in order to provide a quick and complete obturation of the canal.

Technological Characteristics:  

This device has the same technological characteristics and the predicate Obtura device and is operated by the user in the same fashion. The electronics have been updated to comply with current standards and regulations, and the materials and design were selected for better aesthetics and asepsis.
Dear Mr. Conger:

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 (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

[Signature]
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
VI. Indications For Use Statement

510(K) Number:  K 0 4 8 2 8

Device Name: Obtura Heated Gutta Percha System

Indications for Use: The Obtura is intended for use by professionally qualified Licensed dentists, endodontists and clinicians to heat gutta percha and to place it into the previously prepared root canals of human teeth, in order to provide a quick and complete obturation of the canal.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _X_ OR Over-The Counter Use
(Per 21 CFR §801 Subpart D) (21 CFR 807 Subpart C)

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

510(k) Number: k 0 4 2 8 2 8