DEC - 1 2004

II. 510(K) Summary K042828

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 in prepared root canals of teeth during rot 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 in to 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 used 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 update to comply with current standards and regulations, and the materials and design were selected for better aesthetics and asepsis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 1 2004

Mr. Stephen W. Conger
Executive Vice President
Young OS LLC
1663 Fenton Business Park Court
Fenton, Missouri 63026

Re: K042828
Trade/Device Name: Obtura Heated Gutta Percha System
Regulation Number: 872.4562
Regulation Name: Dental Hand Instrument
Regulatory Class: I
Product Code: EKR
Dated: October 7, 2004
Received: October 12, 2004

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.

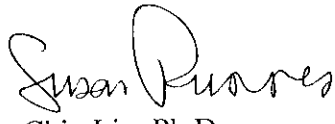
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

VI. **Indications For Use Statement**

510(K) Number: K042828

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: K042828