510(k) SUMMARY

AUG - 5 2003

DENTSPLY

NAME & ADDRESS:

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K031461

CONTACT: P. Jeffery Lehn

DATE PREPARED: MAY 6 2003

TRADE OR PROPRIETARY NAME: CARRIER TIPS

CLASSIFICATION NAME: Accessory to ultrasonic scaler (872.4850)

PREDICATE DEVICES: ProUltra® Endo and Surgical Endo Tips K960889

DEVICE DESCRIPTION:

The CARRIER TIPS are stainless steel ultrasonic tips used to deliver pre-mixed ProRoot® MTA Material to a prepared dental site on the tooth and fill that site as part of an endodontic procedure. There are two tip designs - one for surgical type procedures and one for non-surgical type procedures. These tips and a sleeve are attached to a standard piezo electric ultrasonic scaling unit handpiece. In between placement of the Material, standard hand instruments are used to condense and compact the Material.

INTENDED USE: Used to deliver ProRoot® MTA Material in surgical and non-surgical dental applications in conjunction with an ultrasonic unit.

TECHNOLOGICAL CHARACTERISTICS: CARRIER TIPS are substantially equivalent to ProUltra® Endo Tips and ProUltra® Surgical Endo Tips (K960889). They have the same manufacturer, the same basic technology, the same primary energy source, and are made of the same material as the predicate devices. We believe the similarity of the CARRIER TIPS to the legally marketed predicate devices support the safety and effectiveness of the CARRIER TIPS for the indicated use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 5 2003

Mr. P. Jeffery Lehn
Director of Corporate Compliance and Regulatory Affairs
Dentsply International
570 West College Avenue
P.O. Box 872
York, Pennsylvania 17405-0872

Re: K031461
Trade/Device Name: Carrier Tips
Regulation Number: 872.3820
Regulation Name: Root Canal illing Resin
Regulatory Class: II
Product Code: KIF, ELC
Dated: May 6, 2003
Received: May 8, 2003

Dear Mr. Lehn:

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,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 807.87(e)

510(K) Number (if known): K031461

Device Name: CARRIER TIPS

Indications for Use:

Used to deliver ProRoot® MTA Material in surgical and non-surgical dental applications in conjunction with an ultrasonic unit.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____

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

Susan Runner

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

510(k) Number: K031461