510(k) SUMMARY

FEB 0 7 2003

DENTSPLY

NAME & ADDRESS:

DENTSPLY International
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K030111

CONTACT: P. Jeffery Lehn

DATE PREPARED: JAN 10 2003

TRADE OR PROPRIETARY NAME: DIAMOND COATED INSERTS

CLASSIFICATION NAME: Accessory to dental unit (872.4850)

PREDICATE DEVICES: Diamond Coated Inserts K923639

DESCRIPTION OF DEVICE: DIAMOND COATED INSERTS are coated with a fine grit diamond powder. The diamonds are bonded by an electroplated metallic nickel.

These DIAMOND COATED INSERTS are designed for use in applications where an instrument with aggressive cutting capability is necessary. The inserts are designed to be used with DENTSPLY's Handpieces.

INTENDED USE: Used for: 1) Removal of extremely tenacious deposits of calculus in both non-surgical and surgically exposed cases; 2) Removal of overhangs and re-contouring of dental restorations (amalgam, gold, composite, acrylic and porcelain) in both non-surgical and surgically exposed cases; and 3) Soft tissue debridement--removal of tissue tags, particularly in an intrabony lesions.

TECHNOLOGICAL CHARACTERISTICS: Design modifications made to the DIAMOND COATED INSERTS (K923639) include a change in the grip material and a change in the amount of diamond coating on the inserts. There are no changes in intended use, fundamental scientific technology, or principles of operation.

Because of the nearly equivalent material composition of DIAMOND COATED INSERTS to the predicate device, no biocompatibility testing was necessary.

We believe that these DIAMOND COATED INSERTS are substantially equivalent to those inserts in K923639, and that prior use of the components of DIAMOND COATED INSERTS in legally marketed devices and the data provided support the safety and effectiveness of DIAMOND COATED INSERTS for the intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 07 2003

Mr. P. Jeffery Lehn
Director of Corporate Compliance & Regulatory Affairs
DENTSPLY International
570 West College Avenue
York, Pennsylvania 17404

Re: K030111
Trade/Device Name: Diamond Coated Inserts
Regulation Number: 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: January 10, 2003
Received: January 13, 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, 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): K030111

Device Name: **DIAMOND COATED INSERTS**

Used for:

(1) Removal of extremely tenacious deposits of calculus in both non-surgical and surgically exposed cases;

(2) Removal of overhangs and re-contouring of dental restorations (amalgam, gold, composite, acrylic and porcelain) in both non-surgical and surgically exposed cases; and

(3) Soft tissue debridement--removal of tissue tags, particularly in an intrabony lesions.

This is the same intended use as previously cleared for K923639.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

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

Ron Mutty for MSR

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

510(k) Number: K 030111