510(k) SUMMARY

DENTSPLY

NAME & ADDRESS:

DENTSPLY International
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NOV 0 8 2001

K012720

CONTACT: P. Jeffery Lehn

DATE PREPARED: August 14, 2001

TRADE OR PROPRIETARY NAME: TULSA CONTRA ANGLES

CLASSIFICATION NAME: Dental handpieces and accessories (872.4200)

PREDICATE DEVICES: W&H Series 100 Low Speed K944719

DEVICE DESCRIPTION: The TULSA CONTRA ANGLES are contra angle attachments to handpieces and are manufactured by W&H Dentalwerks GmbH for DENTSPLY Tulsa Dental as Models TUL-1, TUL-8M, and TUL-16MT. These contra angles are designed to transmit the rotational movement of the motor axle to the shank of a bur or file that will be inserted into the output end of the contra angle. These contra angles contain a coupling part fittable to dental motors with a coupling according to ISO 3964. The output ends of the handpieces contain chuck systems for accommodations of standardized bur and file shanks.

INTENDED USE: TULSA CONTRA ANGLES are designed to be used with dental motors for:
Model TUL-1: For endodontic procedures, removing carious material, reducing hard tooth structure, cavity preparations, finishing tooth preparations and restorations, and polishing teeth
Models TUL-8M / TUL16MT - Mechanical root canal preparation with rotating files

TECHNOLOGICAL CHARACTERISTICS: TULSA CONTRA ANGLES are substantially equivalent to those marketed under K944719. They have the same basic technology, primary energy source, and materials as the predicate device.

There are no materials in these contra angles that pose any potential for possible biocompatibility hazard. All of the materials of construction, which come into contact with the patient, are chromium-plated stainless steel.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 8 2001

Mr. P. Jeffrey Lehn
Corporate Compliance
Dentsply International
570 West College Avenue
York, Pennsylvania 17404

Re: K012720
Trade/Device Name: Tulsa Contra Angles
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: August 14, 2001
Received: August 15, 2001

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Rebecca Cucento/for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 807.87(e)

NOV 0 8 2001

K012720

510(K) Number (if known):

Device Name: TULSA CONTRA ANGLES

Indications for Use:

These contra angles are designed to be used with dental motors for :

Model TUL-1: For endodontic procedures, removing carious material, reducing hard tooth structure, cavity preparations, finishing tooth preparations and restorations, and polishing teeth

Models TUL-8M and TUL16-MT: Mechanical root canal preparation with rotating files

(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)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012720