DEC - 4 2003

510(k) SUMMARY

K033705

DENTSPLY

NAME & ADDRESS:

DENTSPLY International
570 West College Avenue
P.O. Box 872
York, PA 17405-0872
(717) 845-7511
~~Fax (717) 849-4762~~
www.dentsply.com

P. J. Lehn Telefax (717) 849-4343

CONTACT: P. Jeffery Lehn

DATE PREPARED: November 24, 2003

TRADE OR PROPRIETARY NAME: BOBCAT® PRO SCALER SYSTEM

CLASSIFICATION NAME: Ultrasonic Scaler 872.4850

PREDICATE DEVICES: G-106 DENTSPLY® Cavitron ® Ultrasonic Dental Unit K834283

DESCRIPTION OF DEVICE: The Modified Device consists of the BOBCAT® Pro Ultrasonic Scaler with handpiece and DENTSPLY's 25K Ultrasonic Inserts.

The Scaler is a 25K ultrasonic scaler that operates over the frequency range of 23.5 - 25.7 kHz. The Scaler is available in various voltage inputs.

INTENDED USE: Used for ultrasonic procedures: 1) All general supra and subgingival scaling applications; 2) Periodontal debridement for all types of periodontal diseases; and 3) Endodontic procedures.

TECHNOLOGICAL CHARACTERISTICS: Design modifications made to the K834283 Unit include changes in electronic components, unit material and handpiece material, and the addition of ultrasonic inserts. The unit uses DENTSPLY's 25K inserts. There are no changes in intended use, fundamental scientific technology, or principles of operation.

All of the materials in the device have been used in legally marketed DENTSPLY devices or found to be safe for dental use.

We believe that the Modified Device is substantially equivalent to K834283, and that prior use of the materials in legally marketed devices and the data provided support the safety and effectiveness of the Modified Device for the intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 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: K033705
Trade/Device Name: Bobcat Pro Scaler System, Model G-130
Regulation Number: 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: November 24, 2003
Received: November 25, 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,

Patricia Cucanti/for

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

INDICATIONS FOR USE STATEMENT

K033705

(As Required by 21 CFR 807.87(e)

510(K) Number (if known): _____

Device Name: **BOBCAT PRO SCALER SYSTEM**

Used for ultrasonic procedures:

- All general supra and subgingival scaling applications
- Periodontal debridement for all types of periodontal diseases
- Endodontic procedures

These are the same intended uses as previously cleared for K834283.

Susan Runyeon

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

510(k) Number: K033705

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)