

K071817

**510(k) SUMMARY**

SEP - 4 2007

DENTSPLY International  
Susquehanna Commerce Center West  
221 West Philadelphia Street, Suite 60  
York, PA 17405-0872

CONTACT: Helen Lewis  
DATE PREPARED: June 25, 2007  
TRADE OR PROPRIETARY NAME: OsteoGraf/N-300  
CLASSIFICATION NAME: Bone Grafting Material 21 CFR 872.3930  
PREDICATE DEVICES: OsteoGraf/N-300, K981182, K960348, K902295

DEVICE DESCRIPTION: The OsteoGraf/N-300 material is a natural, high purity, radiopaque, polycrystalline hydroxylapatite, the major mineral phase of bone and dental enamel. It is manufactured as an anorganic, rounded irregular shaped bovine-derived hydroxylapatite particles, sized at 250-420 microns.

INTENDED USE: Treatment of intrabony periodontal defects, augmentation of bony defects in the alveolar ridge, filling of extraction sites, and sinus elevation grafting.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in OsteoGraf/N-300 have been used in legally marketed devices and/or were found safe for dental use. OsteoGraf/N-300 and the marketed device are biocompatible. OsteoGraf/N-300 conforms to applicable industry standards.

We believe that the prior use of the components of OsteoGraf/N-300 in legally marketed devices, the performance data provided, and biocompatibility support the safety and effectiveness of OsteoGraf/N-300 for the indicated uses.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP - 4 2007

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Helen Lewis  
Director of Corporate Compliance and Regulatory Affairs  
DENTSPLY International, Incorporated  
Susquehanna Commerce Center  
221 West Philadelphia Street  
York, Pennsylvania 17405-0872

Re: K071817  
Trade/Device Name: OsteoGraf/N-300  
Regulation Number: 21 CFR 872.3930  
Regulation Name: Bone Grafting Material  
Regulatory Class: II  
Product Code: LYC  
Dated: August 8, 2007  
Received: August 10, 2007

Dear Ms. Lewis:

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.

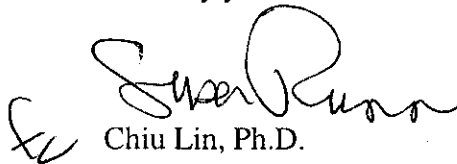
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K071817

Device Name: OsteoGraf/N-300

Indications for Use:

OsteoGraf/N-300 is indicated for treatment of intrabony periodontal defects, augmentation of bony defects in the alveolar ridge, filling of extraction sites, and sinus elevation grafting.

These are the same indications for use previously cleared for K981182.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number: K071817

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