K981214

JUN 26 1998

510(k) SUMMARY

March 31, 1998

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

1. Submitter:
CeraMed Dental, L.L.C.
12860 West Cedar Drive, Suite 110
Lakewood, CO 80228
(303) 985-0800

2. Device Name:
OsteoGraf/N-700 Hydroxylapatite
Classification Name: Endosseous implant for bone filling and/or augmentation

3. Predicate Device:
Bio-Oss

4. Device Description:
OsteoGraf/N-700 is a natural, high purity, radiopaque, polycrystalline form of hydroxylapatite, the major mineral phase of bone and dental enamel. It is manufactured as anorganic, rounded, irregular shaped bovine derived hydroxylapatite particles, sized at 420-1000 microns.

5. Intended Use:

The intended use of OsteoGraf/N-700 is for:

- Treatment of infrabony periodontal defects.
- Augmentation of bony defects of the alveolar ridge.
- Filling of extraction sites.
- Sinus elevation grafting

6. Comparison of Product Characteristics:
OsteoGraf/N-700 consists of 100% anorganic hydroxylapatite, $Ca_{10}(PO_4)_6OH_2$.

X-ray diffraction and infrared analysis (FTIR) show OsteoGraf/N-700 to be 100% hydroxylapatite. OsteoGraf/N-700 conforms to the requirements of ASTM standard #F1581, *Composition of Anorganic Bone for Surgical Implants.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 1998

Mr. Mark Bowerman
Manager, Quality Assurance/Regulatory Affairs
CeraMed Dental L.L.C.
12860 West Cedar Drive
Lakewood, Colorado 80228

Re: K981214
Trade Name: OsteoGraf®/N-700
Regulatory Class: Unclassified
Product Code: LYC
Dated: March 31, 1998
Received: April 2, 1998

Dear Mr. Bowerman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

510(k) Number (if known): K981214

Device Name: OsteoGraf/N-700

Indications For Use:

The intended use of OsteoGraf/N-700 is for:

- Treatment of infrabony periodontal defects.
- Augmentation of bony defects of the alveolar ridge..
- Filling of extraction sites.
- Sinus elevation grafting.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K981214

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)