K033110

DEC 1 0 2003

SECTION 14: SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

14.1 SUBMITTER INFORMATION

a. Company Name:	The Clinician's Preference LLC
b. Company Address:	25188 Gennesse Trail Rd, Suite 150 Golden, CO 80401
c. Company Phone: Company Facsimile:	(303) 526-1041 (303) 526-0695
d. Contact Person:	Michael Czuchna Manager, RA and QA/QC
e. Date Summary Prepared:	September 27, 2003

14.2 DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	C-GRAFT™
b. Classification Name:	Bone filling and augmentation material unclassified
c. Product Code:	LYC

14.3 IDENTIFICATION OF PRECATE DEVICES

Company	Device	510(k) No.	Date Cleared
Interpore International	Interpore® 200 Granular Coralline Hydroxylapatite	K950165	03/28/1995
CeraMed Dental	OsteoGraf® / N-700	K981214	06/26/1998
Friadent GMBH	FRIOS® ALGIPORE®	K023799	02/05/2003

14.4 DEVICE DESCRIPTION

C-GRAFT™ is a bone filling and augmentation material indicated for use in dental applications. C-GRAFT™ is an inorganic, biocompatible calcium phosphate material derived from calcium-encrusted red sea algae. The algae are processed in order to develop an apatite material that is analogous to bone apatite. C-GRAFT™ is provided sterile in pre-filled vials and has a granule size range from 300-1000 microns.

14.5 SUBSTANTIAL EQUIVALENCE

C-GRAFT™ is substantially equivalent to Friadent GMBH FRIOS® ALGIPORE® in terms of material composition, chemical analysis, functionality and intended use. C-GRAFT™ is also substantially equivalent to Interpore International Interpore® 200 Granular Coralline Hydroxylapatite and CeraMed Dental OsteoGraf® / N-700 in terms of material, functionality, and intended use.

14.6 INTENDED USE

C-GRAFT™ is indicated for:

- Treatment of intrabony defects;
- Augmentation of bony defects of alveolar ridge;
- Filling of extraction sites; and
- Sinus elevation grafting.

14.7 TECHNOLOGICAL CHARACTERISTICS

C-GRAFT™ is equivalent to FRIOS® ALGIPORE® in terms of chemical composition. Tests were completed on the two materials to determine the chemical and mineralogical compositions using Inductively Coupled Plasma Mass Spectrometry (ICP-MS) and X-ray Diffraction. Results of the tests show that the materials are equivalent in composition and meet the ASTM standard

specifications for the composition of hydroxylapatite for surgical implants (ASTM F 1185-88).

14.8 CONCLUSIONS

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Review's Checklist is provided with this submission. Performance evaluations of C-GRAFT™ testing reports when compared to those of FRIOS® ALGIPORE® show that the two materials are equivalent both chemically and mineralogically. Comparisons of C-GRAFT™ to the predicate devices show the device to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 0 2003

The Clinician's Preference LLC
Mr. Charles L. Morin
Regulatory counsel
Morin & Associates
388 Market Street, Suite 500
San Francisco, California 94111

Re: K033110
Trade/Device Name: C-GRAFT™
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: LYC
Dated: September 27, 2003
Received: September 30, 2003

Dear Mr. Morin:

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,

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

INDICATION FOR USE

510(k) Number: K033110

Device Name: C-GRAFT™

Indications for Use: C-GRAFT™ is indicated for:

- Augmentation of bony defects of the alveolar ridge
- Sinus elevation grafting
- Treatment of intrabony periodontal defects
- Extraction socket grafting

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEED)

Concurrence of CDRH, office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

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

510(k) Number: K033110