K023796

SECTION 16: SUMMARY OF SAFETY AND EFFECTIVENESS

FEB 0 5 2003

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

16.1 SUBMITTER INFORMATION

a. Company Name:	FRIADENT GmbH.
b. Company Address:	Steinzeugstrasse 50 Mannheim D-68229 Germany
c. Company Phone: Company Facsimile:	(011) 49 621 43 02 1121 (011) 49 621 43 02 2121
d. Contact Person:	Heike Dietzler Regulatory Affairs Manager
e. Date Summary Prepared:	November 11, 2002

16.2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	FRIOS® ALGIPORE®
b. Classification Name:	Bone Filling and Augmentation Material Unclassified
c. Product Code:	LYC

16.3 IDENTIFICATION OF PREDICATE 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

16.4 DEVICE DESCRIPTION

FRIOS® ALGIPORE® is a bone filling and augmentation material indicated for use in dental applications. FRIOS® ALGIPORE® is an inorganic, biocompatible calcium phosphate material derived from calcium-encrusted sea algae. The algae are processed in order to develop an apatite material that is analogous to bone apatite. FRIOS® ALGIPORE® is provided sterile in pre-filled vials and has a granular size range from 300 – 2000 microns.

16.5 SUBSTANTIAL EQUIVALENCE

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

16.6 INTENDED USE

FRIOS® ALGIPORE® is indicated for:

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

16.7 TECHNOLOGICAL CHARACTERISTICS

FRIOS® ALGIPORE® is equivalent to Interpore 200 in terms of chemical composition. Comparison testing of the two materials was performed to determine the chemical and mineralogical composition using Inductively Coupled Argon Plasma Atomic Emission Spectroscopy (ICP-AES) and X-Ray Diffraction. Results of the testing showed that the materials are equivalent in composition and meet the ASTM standard specifications for the composition of Hydroxylapatite for surgical implants.

16.8 CONCLUSIONS

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission. Performance evaluations of the FRIOS® ALGIPORE® when tested in comparison to Interpore® 200 show that the materials are equivalent. Comparisons of the FRIOS® ALGIPORE® to the predicate devices show that the device is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 5 2003

FRIADENT GmbH
C/O Ms. Carol Patterson
President
Patterson Consulting Group, Incorporated
21911 Erie Lane
Lake Forest, California 92630

Re: K023799
Trade/Device Name: FRIOS® ALGIPORE®
Regulation Number: None
Regulation Name: Bone Filling and Augmentation Material
Regulatory Class: Unclassified
Product Code: LYC
Dated: November 11, 2002
Received: November 14, 2002

Dear Ms. Patterson:

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,

Susan Runner

Susan Runner, DDS, MA
Interim 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:

Device Name: FRIOS® ALGIPORE®

Indications for Use: FRIOS® ALGIPORE® is indicated for:

- Treatment of intrabony defects
- Augmentation of bony defects of 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)

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

Lori Mulley for NSR

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

510(k) Number: K023799