OCT 27 2004

K040170

SECTION 16: 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.

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 06 21 4 86 1549 (011) 49 06 21 4 86 1866
d. Contact Person:	Heike Dietzler Regulatory Affairs Manager
e. Date Summary Prepared:	September 28, 2004

16.2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	FRIALIT® PLUS Dental Implant System XiVE® S PLUS Dental Implant System XiVE® TG PLUS Dental Implant System XiVE® D 3.0 PLUS Dental Implant System
b. Classification Name:	Endosseous Dental Implants 21 CFR 872.3640

16.3 IDENTIFICATION OF PREDICATE DEVICES

Company	Device	510(k) No.	Date Cleared
FRIADENT GmbH	FRIALIT® Dental Implant System	K031671	08/14/2003
	XiVE® S Dental Implant System	K032158	08/14/2003
	XiVE® TG Dental Implant System	K032284	08/14/2003
	XiVE® D 3.0 Dental Implant System	K032302	10/02/2003

16.4 DEVICE DESCRIPTION

The FRIALIT®, XiVE® and XiVE® TG dental implants with the new FRIADENT Surface have been cleared for commercial distribution. The purpose of this application is to change the name of the surface to PLUS and obtain clearance for additional marketing claims associated with the PLUS surface.

16.5 SUBSTANTIAL EQUIVALENCE

The FRIADENT® PLUS Dental Implant Systems are substantially equivalent to the current FRIADENT® Dental Implant Systems in terms of design, materials, coatings, mechanical strength, prosthetic options and single tooth intended use.

16.6 INTENDED USE

The FRIALIT® PLUS Dental Implant System is indicated for use in single tooth restorations, edentulous spans restored with multiple single teeth, freestanding bridges and to retain overdentures. The implants can be used for immediate implant placement, delayed immediate or late implant placement.

The XiVE® S PLUS Dental Implant System is indicated for the following: Once the implant has osseointegrated, it serves to support single tooth, bridge and overdenture restorations. In the edentulous mandible, a minimum of four XiVE® dental implants (≥9.5mm length) are placed between the mental foramina and rigidly splinted together. In this case, bar prosthetic loading is possible immediately after implant placement.

The XiVE® D3.0 PLUS Dental Implant System is indicated for single tooth restorations and splinted tooth restorations in the region of 7 to 10 and 23 to 26.

The XiVE® TG PLUS Dental Implant System is indicated for single-stage implant placement, with a minimum healing phase of three months in good quality bone and four months in spongy bone, for maxillary and mandibular splinted crowns, bridges and bar-retained overdenture restorations. The bridge must be supported by a minimum of two transgingival threaded implants. In the edentulous maxilla, a minimum of four transgingival implants are placed in a trapezoidal distribution

and rigidly splinted together. In the edentulous mandible, a minimum of four transgingival implants (≥9.5mm length) are placed between the mental foramina and rigidly splinted together. In this case, bar prosthetic loading is possible immediately after implant placement.

16.7 TECHNOLOGICAL CHARACTERISTICS

Preclinical evaluations of the FRIADENT PLUS Surface were conducted at the University of Tübingen, Germany. Several studies were conducted to determine the physiochemical surface characteristics in comparison to other commercially available surfaces.

Animal studies of the FRIADENT PLUS Surface were conducted at the University of Cologne, Germany, and the University of São Paulo, Brazil. Studies involved the evaluation of loaded and unloaded implants in pigs, immediate implant placement in periodontally infected sites, and the effect of visible and NIR low intensity laser therapy on implant osseointegration.

Results of these studies support the PLUS surface characteristics, name and advertising claims for the FRIADENT Dental Implant Systems.

16.8 CLASS III CERTIFICATION AND SUMMARY

This notification contains a Class III certification and summary of adverse safety and effectiveness information pursuant to 513(f) of the Federal Food, Drug, and Cosmetic Act.

16.9 CONCLUSIONS

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewers Checklist is provided in this submission. Preclincal evaluations and animal studies of the FRIADENT PLUS surface have been presented to substantiate the name PLUS and associated marketing claims. Comparison of the FRIADENT dental implant systems to the predicate device shows that the device is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 2004

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

Re: K040170
Trade/Device Name: FRIADENT PLUS Dental Implant Systems
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: July 28, 2004
Received: August 11, 2004

Dear Ms. White:

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.

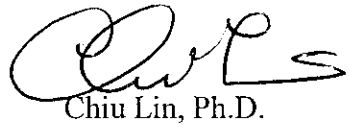
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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/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: K040170

Device Name: FRIADENT PLUS Dental Implant Systems

Indications for Use:

The FRIALIT® PLUS Dental Implant System is indicated for use in single tooth restorations, edentulous spans restored with multiple single teeth, freestanding bridges and to retain overdentures. The implants can be used for immediate implant placement, delayed immediate or late implant placement.

The XiVE® PLUS Dental Implant System is indicated for the following: Once the implant has osseointegrated, it serves to support single tooth, bridge and overdenture restorations. In the edentulous mandible, a minimum of four XiVE® dental implants (≥11mm length) are placed between the mental foramina and rigidly splinted together. In this case, bar prosthetic loading is possible immediately after implant placement.

The XiVE® D3.0 PLUS Dental Implant System is indicated for single tooth restorations and splinted tooth restorations in the region of 7 and 10 and 23 to 26.

(continue next page)

Prescription Use ___X___ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

510(k) Number K040170

INDICATION FOR USE
(Continued)

510(k) Number: K040170

Device Name: PLUS Dental Implant Systems

Indications for Use: (continued)

The XiVE® TG PLUS Dental Implant System is indicated for single-stage implant placement, with a minimum healing phase of three months in good quality bone and four months in spongy bone, for maxillary and mandibular splinted crowns, bridges and bar-retained overdenture restorations. The bridge must be supported by a minimum of two transgingival threaded implants. In the edentulous maxilla, a minimum of four transgingival implants are placed in a trapezoidal distribution and rigidly splinted together. In the edentulous mandible, a minimum of four transgingival implants (≥11mm length) are placed between the mental foramina and rigidly splinted together. In this case, bar prosthetic loading is possible immediately after implant placement.

FRIADENT PLUS grit-blasted and high temperature acid-etched implants display higher removal torque values compared to solely acid-etched implants and anodic oxidized textured implants. The high removal torque values of FRIADENT PLUS implants after a loading period of 5 months may be interpreted as an increase in the strength of endosseous implant integration and implant stability.

Prescription Use ___X___ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)