K030639

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:	February 27, 2003

16.2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	XiVE® 3.0 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-2 3.4mm Dental Implant with Deep Profile Surface	K994376	03/24/2000

16.4 DEVICE DESCRIPTION

The XiVE 3.0 Dental Implant System consists of subgingival threaded dental implants with a 3.25mm diameter and lengths of 11 – 15mm . The implants are coated with the FRIOS Deep Profile Surface. The XiVE Dental Implant System

is comprised of dental implants, surgical and laboratory instruments and prosthetic components. The system is designed for two stage procedures for single tooth replacement in the anterior regions of the mouth.

16.5 SUBSTANTIAL EQUIVALENCE

The XiVE® 3.0 dental implant is substantially equivalent to the current FRIALIT-2® 3.4mm Dental Implant Systems in terms of design, materials, coatings, mechanical strength, prosthetic options and single tooth intended use.

16.6 INTENDED USE

The XiVE 3.0 Dental Implant System is indicated for single tooth restorations in the region of 7 to 10 and 23 to 26.

16.7 TECHNOLOGICAL CHARACTERISTICS

The XiVE® 3.0 dental implant is identical to the current FRIALIT-2® 3.4mm dental implants in terms of coatings, materials and prosthetic options. The XiVE® 3.0 dental implant is 3.25mm diameter screw-type implant with FRIOS® Deep Profile Surface. The lengths of the implants range from 11 – 15mm. The XiVE 3.0 dental implants are constructed of CP-2 titanium. A variety of prosthetic options are available for the XiVE 3.0 system including EstheticBase, AuroBase, Select and Telescopic Abutments. The XiVE 3.0 dental implant system was tested for compressive and static strength and finite element analysis.

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) Reviewer's Checklist is provided in this submission. Performance evaluations of the XiVE 3.0 dental implant system show that the device performs as intended for the anterior region of the mouth. Comparison of the XiVE 3.0 dental implant system to the predicate device 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

AUG 12 2003

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

Re: K030639
Trade/Device Name: XiVE® 3.0 Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: July 23, 2003
Received: July 25, 2003

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, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number: K030639

Device Name: XiVE® 3.0 Dental Implant System

Indications for Use: The XiVE 3.0 Dental Implant System is indicated for single tooth restorations and splinted tooth restorations in the region of 7 to 10 and 23 to 26.

(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)

Kevin Mulhq for MSN
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K 03 0639