K024004

MAR 0 3 2003

SECTION 18: 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.

18.1 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:	February 23, 2003

18.2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	XiVE® Transgingival Dental Implant System
b. Classification Name:	Endosseous Dental Implants 21 CFR 872.3640

18.3 IDENTIFICATION OF PREDICATE DEVICES

Company	Device	510(k) No.	Date Cleared
FRIADENT GmbH	FRIALOC® Dental Implant System	K013067	04/09/2002
FRIADENT GmbH	XiVE® Dental Implant System	K013867	03/15/2002

18.4 DEVICE DESCRIPTION

The XiVE® Transgingival Dental Implant System consists of transgingival threaded dental implants in 3.4 - 5.5mm diameters with 8 – 18mm lengths. The implants are coated with the FRIOS Deep Profile Surface. The XiVE® Transgingival Dental Implant System is comprised of dental implants, surgical and laboratory instruments and prosthetic components. The system is designed for single stage procedures for single tooth replacement, fixation of bridges and complete dentures and for immediate loading indications in the edentulous mandible.

18.5 SUBSTANTIAL EQUIVALENCE

The XiVE® transgingival dental implant is substantially equivalent to the FRIALOC® Dental Implant Systems in terms of design, materials, coatings, mechanical strength, and intended use. The XiVE® transgingival dental implant is substantially equivalent to the current XiVE® dental implant in terms of materials, coatings, prosthetic options, and intended use.

18.6 INTENDED USE

The XiVE® Transgingival 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 $\geq$ 9.5mm are placed between the mental foramina and rigidly splinted together. In this case, bar-prosthetic loading is possible immediately after implant placement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 3 2003

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

Re: K024004
Trade/Device Name: XiVIE® Transgingival Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implants
Regulatory Class: III
Product Code: DZE
Dated: February 6, 2003
Received: February 7, 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 Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number: K024004

Device Name: XiVE® Transgingival Dental Implant System

Indications for Use: The XiVE® Transgingival 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 are placed between the mental foramina and rigidly splinted together. In this case, bar-prosthetic loading is possible immediately after implant placement.

(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 Mulloy for MSK

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

510(k) Number: K024004