

K994376

MAR 24 2000

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: (011) 49 06 21 4 86 1549
Company Facsimile: (011) 49 06 21 4 86 1866
- d. Contact Person: Birgit Unger
Quality Management and Regulatory Affairs
- e. Date Summary Prepared: December 21, 1999

16.2. DEVICE IDENTIFICATION

- a. Trade/Proprietary Name: FRIALIT-2® 3.4mm Dental Implant
- b. Classification Name: Endosseous Dental Implants
21 CFR 872.3640

16.3 IDENTIFICATION OF PREDICATE DEVICES

<u>Company</u>	<u>Device</u>	<u>510(k) No.</u>	<u>Date Cleared</u>
Nobel BioCare	Branemark System Standard 3.75mm Fixture	K925765	10/05/93

16.4 DEVICE DESCRIPTION

The FRIALIT-2® 3.4mm Dental Implant is an addition to the FRIALIT-2® Dental Implant System currently in commercial distribution. The FRIALIT-2® 3.4mm dental implant is available as a stepped cylinder coated with either FRIOS® TPS (titanium plasma sprayed) coating or FRIOS® HA (hydroxylapatite) coating, and a stepped screw-type implant line coated with the FRIOS® Deep Profile Surface. Surgical, prosthetic and laboratory components to facilitate the placement and restoration of the 3.4mm implant have also been designed.

16.5 SUBSTANTIAL EQUIVALENCE

The FRIALIT-2® 3.4mm dental implant is substantially equivalent to the current FRIALIT-2® Dental Implant Systems in terms of design, materials, coatings and prosthetic options. The FRIALIT-2® 3.4mm dental implant is substantially equivalent to the Nobel BioCare Branemark 3.75mm dental implant in terms of 30° Compression/Bending Testing and Cyclic Loading Fatigue Testing.

The FRIALIT-2® 3.4mm dental implant is equivalent to the current FRIALIT-2® dental implants in design, materials, coatings, prosthetics, function and intended use. The FRIALIT-2® 3.4mm dental implant is equivalent to the Nobel BioCare Branemark 3.75mm dental implant in materials, functionality, mechanical strength and intended use.

16.6 INTENDED USE

The FRIALIT-2® 3.4mm dental implant is intended for use in single tooth restoration, edentulous spans restored with multiple single teeth, freestanding bridges and to retain overdentures. The implants can be used after extraction for immediate implant placement, delayed immediate implant placement or late implant placement.

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16.7 TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the FRIALIT-2® 3.4mm dental implant with the predicate devices is provided within this submission. The FRIALIT-2® 3.4mm dental implant is identical to the current FRIALIT-2® dental implants in terms of coatings, materials, prosthetic options and intended use. The FRIALIT-2® 3.4mm dental implant is available in a stepped cylinder with either FRIOS® TPS or FRIOS® HA coating, and as a stepped screw-type with FRIOS® Deep Profile Surface.

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.

16.9 510(K) CHECKLIST

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.

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4690. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



MAR 24 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K994376
Trade Name: FRIALIT-2® Dental Implant System
Regulatory Class: III
Product Code: DZE
Dated: December 21, 1999
Received: December 27, 1999

Dear Ms. Patterson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any

INDICATION FOR USE

510(k) Number: K994376

Device Name: FRIALIT-2® Dental Implant System

Indications for Use: The FRIALIT-2® Dental Implant System is intended for use in single tooth restoration, edentulous spans restored with multiple single teeth, free-standing bridges and to retain overdentures. The implants can be used after extraction for immediate implant placement, delayed immediate implant placement or late implant placement.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K994376

Prescription Use

OR

Over-The-Counter Use

(Per 21 CFR 801.109)