

DEC - 9 1999

FRIADENT GmbH FRIALIT-2 Select Components
Original Premarket 510(k) Notification

K99 3095

SECTION 14: 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.

14.1 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: September 10, 1999

14.2. DEVICE IDENTIFICATION

- a. Trade/Proprietary Name: FRIALIT-2 Select Components
Accessories to the FRIALIT-2 Dental
Implant Systems
- b. Classification Name: Endosseous Dental Implants
21 CFR 872.3640

14.3 IDENTIFICATION OF PREDICATE DEVICES

<u>Company</u>	<u>Device</u>	<u>510(k) No.</u>	<u>Date Cleared</u>
Implant Innovations	3i Standard Threaded and	K950204	09/27/95

14.4 DEVICE DESCRIPTION

The FRIALIT-2 Select Components are part of the FRIALIT-2 Dental Implant System. The components consist of the FRIALIT-2 Select Sleeve, FRIALIT-2 Select Try-in Implant, and FRIALIT-2 Select try-in Abutment. The components come in the same diameters as the implant bodies and are color coded to correspond to size. The components can be used in the patient and/or the laboratory model to help in the determination of implant placement, abutment and implant angle and available soft tissue height.

14.5 SUBSTANTIAL EQUIVALENCE

The FRIALIT-2 Select Components are substantially equivalent to the Implant Innovations, Inc., Pre-angled Surgical and Prosthetic Guide Kits and Tissue Measuring Post Components of the 3i Standard Threaded/Self-Tapping Threaded Dental Implant Systems.

The fundamental technical characteristics of the FRIALIT-2 Select Components are similar to those of the predicate. The FRIALIT-2 Select Components are equivalent to the Implant Innovations, Inc., components in design, material, and functionality.

14.6 INTENDED USE

The FRIALIT-2 Dental Implant System is intended for single tooth restorations, edentulous spans restored with multiple single teeth, free-standing bridges and to retain overdentures. These implants can be used for immediate, delayed immediate or late implant placement.

14.7 TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the FRIALIT-2 Select Components with the predicate device is provided within this submission. Both the FRIALIT-2 Select Components and the predicate device are similar in design, materials and functionality. The FRIALIT-2 Select components are available in diameters corresponding to those of the implant bodies. The components are color-coded for ease of use.

14.8 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.

14.9 510(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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 9 1999

Friadent GmbH
Ms. Carol Patterson
Consultant for Friadent GmbH
Patterson Consulting Group, Inc.
21911 Erie Lane
Lake Forest, CA 92630

Re: K993095
Trade Name: Frialit-2 Select Components
Regulatory Class: III
Product Code: DZE
Dated: September 10, 1999
Received: September 16, 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.

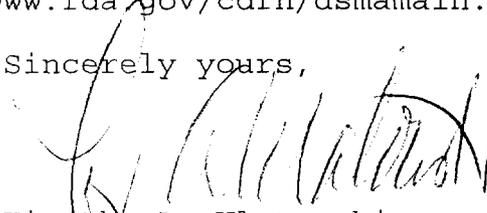
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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

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) 594-4692. 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

FRIADENT GmbH FRIALIT-2 Select Components
Original Premarket 510(k) Notification

INDICATION FOR USE

510(k) Number: To Be Assigned By FDA

Device Name: FRIALIT-2® Select Components

Indications for Use: The Select Components of the FRIALIT-2® Dental Implant System are indicated for use in the determination of implant placement, implant angle and to measure the available soft tissue height. The Select Components can also be used in determining the potential abutment angle and soft tissue height.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Pinner

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

510(k) Number K992095

Prescription Use

OR

Over-The-Counter Use

(Per 21 CFR 801.109)

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