

K994174

APR 20 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 8, 1999

16.2. DEVICE IDENTIFICATION

- a. Trade/Proprietary Name: FRIALIT-2® MH-2 Abutment
Accessories to the FRIALIT-2 Dental
Implant Systems
- 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>
FRIADENT	FRIALIT-2® Stepped Cylinder With FRIOS® Coating System	K945849	03/15/96
Nobel BioCare	Branemark Self-Tapping MK II Dental Implant System	K962130	07/22/96

16.4 DEVICE DESCRIPTION

The FRIALIT-2® MH-2 Abutment is part of the FRIALIT-2® Dental Implant System. The MH-2 Abutment is designed to support multiple unit bridges and bar overdentures. The MH-2 Abutment is constructed of CP-2 titanium and is available in the same diameters as the FRIALIT-2® implant bodies. Each MH-2 Abutment diameter is available with a 1, 2, 3, or 5mm gingival cuff height. The 3.8 and 4.5mm abutments are also available with a 9mm gingival cuff height.

16.5 SUBSTANTIAL EQUIVALENCE

The FRIALIT-2® MH-2 Abutment is substantially equivalent to the current MH-2 Abutment of FRIADENT's FRIALIT-2® Dental Implant Systems and to the Nobel BioCare Abutment of the Self-Tapping Mk II Dental Implant System.

The fundamental technical characteristics of the FRIALIT-2® MH-2 Abutment are similar to those of the predicate. The proposed FRIALIT-2® MH-2 Abutment is equivalent to the current MH-2 Abutment in material, function and intended use. The FRIALIT-2® MH-2 Abutment is equivalent to the Nobel BioCare Abutment in design, functionality and intended use.

16.6 INTENDED USE

The FRIALIT-2® MH-2 Abutment is intended for use in multiple unit bridges and bar overdentures.

16.7 TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the FRIALIT-2® MH-2 Abutment with the predicate devices is provided within this submission. Both the FRIALIT-2® MH-2 Abutment and the predicate devices are similar in design, materials and functionality. The FRIALIT-2® MH-2 Abutment is available in

diameters corresponding to those of the implant bodies. Each MH-2 Abutment diameter is available with a 1, 2, 3, or 5mm gingival cuff height. The 3.8 and 4.5mm diameter MH-2 Abutment is also available with a 9mm gingival cuff height.

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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 20 2000

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

Re: K994174
Trade Name: FRIALIT-2® MH-2 Abutment
Regulatory Class: III
Product Code: DZE
Dated: March 9, 2000
Received: March 15, 2000

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 premarket notification submission does not affect any

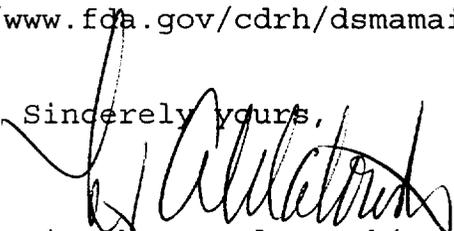
Page 2 -Ms. Patterson

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

INDICATION FOR USE

510(k) Number: To Be Assigned By FDA

Device Name: FRIALIT-2® MH-2 Abutment

Indications for Use: The FRIALIT-2® MH-2 Abutment is intended for use in multiple unit bridges and bar overdentures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

S. L. Shire, D.M.D. for MSR

(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K994174

Prescription Use OR Over-The-Counter Use
(Per 21 CFR 801.109)