



MAR 30 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K013438
Trade/Device Name: Frialit-2 Estheticbase Abutment
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: III
Product Code: NHA
Dated: October 15,2001
Received: October 17,2001

Dear Ms. Patterson:

This letter corrects our substantially equivalent letter of December 20,2001 regarding the company name.

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 (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 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 continue 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 (240) 276-0115. 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,



Chiu Lin, Ph.D.
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: To Be Assigned By FDA

Device Name: FRIALIT-2® EstheticBase Abutment

Indications for Use: The FRIALIT-2® EstheticBase Abutment is intended for use to fabricate screw-retained or cementable crowns and bridges.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

A. Blackwell for M.S. Runner
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013438

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

CONFIDENTIAL

DEC 2 0 2001

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:** Heike Dietzler
Regulatory Affairs Manager
- e. **Date Summary Prepared:** October 15, 2001

16.2. DEVICE IDENTIFICATION

- a. **Trade/Proprietary Name:** FRIALIT-2® EstheticBase Abutment
Accessories to the FRIALIT-2® Dental
Implant Systems
- b. **Classification Name:** Endosseous Dental Implants
21 CFR 872.3640

163 IDENTIFICATION OF PREDICATE DEVICES

<u>Company</u>	<u>Device</u>	<u>510(k) No.</u>	<u>Date Cleared</u>
Nobel BioCare	TiAdapt Abutment System	K971706	07/21/1997

16.4 DEVICE DESCRIPTION

The **FRIALIT-2® EstheticBase** Abutment is part of the **FRIALIT-2® Dental Implant System**. The **EstheticBase Abutment** is intended for the fabrication of screw-retained or **cementable** crowns and bridges. The **EstheticBase** Abutment is constructed of CP-2 titanium and is available in the same **diameters** as the **FRIALIT-2®** implant **bodies**. Each **EstheticBase** Abutment diameter is available with a **1, 2, 3, or 5mm** gingival cuff height. The **EstheticBase** Abutment is available with a **straight** or angled **configuration**.

16.5 SUBSTANTIAL EQUIVALENCE

The **FRIALIT-2® EstheticBase** Abutment is substantially equivalent to the Nobel **BioCare TiAdapt** Abutment System.

The **fundamental** technical characteristics of the **FRIALIT-2® EstheticBase** Abutment and components are similar to those of the predicate. The **FRIALIT-2 9 EstheticBase** Abutment is equivalent to the Nobel **BioCare TiAdapt** Abutment in design, **functionality**, materials and intended use.

16.6 INTENDED USE

The **FRIALIT-2® EstheticBase** Abutment is intended for use in the fabrication of screw-retained and **cementable** crowns and bridges.

16.7 TECHNOLOGICAL CHARACTERISTICS

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

implant bodies. Each EstheticBase Abutment diameter is available with a 1, 2, 3, or 5mm gingival cuff height and in a straight or angled configuration.

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.