

SEP 4 1998

K980630

Premarket Notification 510(k)
 Article Name: FRIALIT-2® CeraBase Abutment



XI. 510(k) Summary of Safety and Effectiveness

XI.1. Submitter Information

Submitter: FRIATEC AG, Medical Technology Division
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Date Prepared: February 2nd, 1998

XI.2. Name of Device

Proprietary Name: FRIALIT-2® CeraBase abutment
Common Name: Ceramic abutment for endosseous implants
Classification Name: Endosseous implants

XI.3. Predicate Device Information

Name: CeraOne Abutment
Submitter: NobelBioCare USA, Inc.
510(k) Number: K961737

XI.4. Description of the Device

The FRIALIT-2® CeraBase abutment is a two part abutment. It consists of the titanium insert and the ceramic sleeve. The titanium insert has as the rotational securing device a hexagon, which is the counterpart to the internal hexagon of the FRIALIT-2® implant. The ceramic sleeve is placed on top of the titanium insert where it is rotationally secured by a slot and key connection. The titanium insert is color-coded in order to clearly differentiate the different diameters.

The diameters of the FRIALIT-2® CeraBase abutments correspond to the FRIALIT-2® implant diameters. The following diameters are available:

D3,8 mm, D4,5 mm, D5,5 mm and D6,5 mm.

The FRIALIT-2® CeraBase titanium insert is manufactured out of pure titanium grade II material which is in accordance to ASTM F 67 'Standard Specification for Unalloyed Titanium for Surgical Implant Application'.

The FRIALIT-2® CeraBase ceramic sleeve is manufactured out of medical grade aluminumdioxid ceramic which is in accordance to ASTM F 603 'Standard Specification for High-Purity Dense Aluminum Oxide for Surgical Implant Application'.

XI.5. Intended Use

The FRIALIT-2® CeraBase abutment is intended for use of the following indications:

Fabrication of single crowns for the anterior maxilla and mandible where exceptional esthetics are required.

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XI.6. Technological Characteristics

The technological characteristics of the FRIALIT-2® CeraBase abutment are substantially the same as the characteristics of the NobelBioCare CeraOne abutment. Both devices consist of two single parts. One part of each is an insert or abutment made of medical grade titanium. The second part of each device is a sleeve or cap composed of aluminumdioxide ceramic. Thus, the material of construction is identical for the FRIALIT-2® CeraBase and the NobelBioCare CeraOne devices (i.e. titanium and aluminumdioxide). For rotation, both devices use a hexagon that complements the internal or external hexagon of the implant.

The tables below show technological properties and preclinical testing results for both the FRIALIT-2® CeraBase and the predicate device.

Properties	FRIALIT-2® CeraBase abutment	NobelBioCare CeraOne abutment
Al2O3 content	99,6 weight-%	99,0 weight-%
crystallogical phase	α-aluminumdioxide	α-aluminumdioxide
grain size parameters [µm]	d10 d50 d90 1,3 3,9 7,7	d10 d50 d90 0,9 2,2 3,8

Preclinical Tests	FRIALIT-2® CeraBase abutment	NobelBioCare CeraOne abutment
static shear strength [lbs]	98,2	74,5
dynamic fatigue strength [lbs]	runout at 35 [lbs]	runout at 35 [lbs]



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 4 1998

FRIATEC AG
C/O Darcy J. Madden, M.S., M.B.A., R.A.C.
Regulatory Affairs Associate
Authorized Regulatory Agent for FRIATEC AG
Advanced Bioresearch Associates
ABA SAN DIEGO
One America Plaza
600 West Broadway, Suite 900
San Diego, California 92101-3302

Re: K980630
Trade Name: FRIALIT-2® CeraBase
Regulatory Class: III
Product Code: DZE
Dated: June 5, 1998
Received: June 8, 1998

Dear Ms. Madden:

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 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). 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.

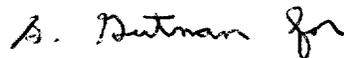
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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 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" (21CFR 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/dsma/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

510(k) Number (if known); _____

Device Name: FRIALIT-2(r) CeraBase

Indications For Use:

The FRIALIT-2(r) CeraBase abutment is intended for use in the fabrication of single crowns for the anterior maxilla and mandible where exceptional esthetics are required.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

Susan Penn
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number KT5063U