

OCT 22 1998

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

K982576



## VIII. 510(k) Summary of Safety and Effectiveness

### VIII.1. Submitter Information

**Submitter:** FRIATEC AG, Medical Technology Division  
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68229 Mannheim / Germany  
**Contact Person:** Birgit Unger (QA/RA Manager)  
**Telephone:** 011-49-621-486-1549  
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**Data Prepared:** July 7th, 1998

### VIII.2. Name of Device

**Proprietary Name:** FRIALIT-2® AuroBase abutment  
**Common Name:** Abutment for endosseous implants  
**Classification Name:** Endosseous Implant

### VIII.3. Predicate Device Information

**Name:** UCLA abutment  
**Submitter:** 3i Implant Innovations Incorporated  
**510(k) Number:** K874400

### VIII.4. Description of the Device

The FRIALIT-2® AuroBase abutment is a one part abutment with two working areas, a gold cylinder and a plastic sleeve. The gold cylinder has as the rotational securing device a hexagon, which is the counterpart to the internal hexagon of the FRIALIT-2® implant. The plastic sleeve molded around the gold cylinder and is color-coded in order to differentiate the different diameters.

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

Ø3,8 mm, Ø4,5 mm, Ø5,5 mm and Ø6,5 mm.

The FRIALIT-2® AuroBase gold cylinder is manufactured out of a commercial gold alloy. The FRIALIT-2® AuroBase plastic sleeve is manufactured out of a burnable commercial plastic.

### VIII.5. Intended Use

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

- fabrication of multiple unit restorations
- fabrication of single tooth restorations
- custom abutment fabrication,
- fabrication of laboratory-constructed angled abutments

### VIII.6. Technological Characteristics

The technological characteristics of the FRIALIT-2® AuroBase abutment are substantially the same as the characteristics of the 3i UCLA abutment. Both devices consist of two working areas. One working area is the gold cylinder, the second working area is the plastic sleeve for the modelling of the later individualized abutment. The material of construction is identical for the FRIALIT-2® AuroBase and the 3i UCLA abutment. For anti-rotation, both devices use a hexagon that complements the internal or external hexagon of the implant.

The tables below show technological and preclinical testing results for both the FRIALIT-2® AuroBase and the 3i UCLA abutment.

Composition Gold Cylinder	FRIALIT-2® AuroBase	3i UCLA abutment
Au	57,8	58,0
Pd	21,0	19,5
Pt	19,6	21,1
Ir	1,6	1,7

**Table #VIII.1:** Chemical Composition of the gold cylinder FRIALIT-2® AuroBase and 3i UCLA abutment

Preclinical Tests	FRIALIT-2® AuroBase	3i UCLA abutment
static shear strength [lbs]	110,6	81,7
dynamic fatigue strength [lbs]	runout at 40	runout at 40

**Table #VIII.2:** Preclinical tests of FRIALIT-2® AuroBase and 3i UCLA abutment



OCT 22 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FRIATEC AG  
C/O R. Steve Reitzler, RAC, Vice President, Regulatory Affairs  
Advanced Bioresearch Associates  
ABA SAN DIEGO  
One America Plaza  
600 West Broadway, Suite 900  
San Diego, California 92101-3302

Re: K982576  
Trade Name: FRIALIT-2® AuroBase Model Numbers 45-2446,  
45-2456, 45-2466  
Regulatory Class: III  
Product Code: DZE  
Dated: July 24, 1998  
Received: July 24, 1998

Dear Mr. Reitzler:

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.

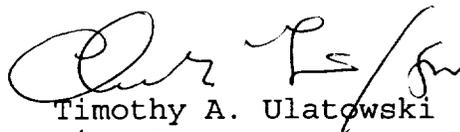
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Indications for Use:

**THE FRIALIT-2® AUROBASE ABUTMENT IS INTENDED FOR USE IN FABRICATION OF MULTIPLE UNIT RESTORATIONS, SINGLE TOOTH RESTORATIONS, CUSTOM ABUTMENTS AND LABORATORY-CONSTRUCTED ANGLED ABUTMENTS IN THE MAXILLA AND MANDIBLE.**

(PLEASE DO NOT WRITE BELOW THIS LINE IN 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)

*Michael S. ...*  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K 982576