SEP 2 9 1999

K991947

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510(k) SUMMARY
3i Ceramic Abutments

To 510(k) Summary Requestor:

Information contained in this summary is from an original Pre-Market Notification [510(k)] submission, provided the United States Food and Drug Administration. No pertinent or known releasable information regarding device safety or efficacy has been intentionally or otherwise knowingly deleted from that submission, for this summary.

William G. Conety
Regulatory Affairs

CLASSIFICATION NAME: Endosseous Dental Implant

COMMON/USUAL NAMES: Abutments; transmucosal abutments/elements

PROPRIETARY NAME: No established marketing name at time of submission.

CLASSIFICATION: Class III

PERFORMANCE STANDARDS: No established performance standards for abutments

FORM and CONSTRUCTION: The 3i ceramic abutment is comprised of three basic components: An outer cylinder or sleeve constructed from zirconium ceramic bonded to an inner machined titanium alloy core with a biocompatible, water-insoluble, apatite glass-ceramic sealer.

Titanium alloy cores or inserts are machined. The ceramic sleeve is molded. The two components are bonded using proprietary process. After bonding, parts are cleaned, inspected, packaged and sterilized. Sterilization is accomplished by gamma irradiation to a SAL of 10^{-6}.
The 3i ceramic abutment is equivalent in physical strength characteristics as other devices.

Cyclical Fatigue at 30° Angle (Average result)

Other device	3i
5000000 cycles @ 250 N	5000000 cycles @ 300 N

Static load at 30° Angle (Average result)

Other device	3i
517 N	695 N

03 Torsional Strength (Average result)

Other device	3i
79.5 Ncm [1]	166 Ncm [2]
[1] Abutment hex failed	[2] Implant hex failed

In all physical testing undertaken, the 3i ceramic abutment performed as well or better than equivalent other devices.

SUBSTANTIAL EQUIVALENCE: The 3i ceramic abutment is substantially equivalent to Nobel Biocare "CerAdapt" abutment in that they are similar in outward appearance, basic design configuration and indications for use do not differ between the two.

The Nobel Biocare device is a one-piece aluminum oxide ceramic device. The 3i ceramic abutment is a three component device: Inner titanium sleeve and outer ceramic body, bonded by a compatible ceramic.

INDICATIONS: Ceramic abutments are indicated for use with endosseous dental implants, to extend implant's coronal aspect through mucosal tissues and into the oral cavity, for prosthetic attachment. Ceramic abutments are primarily indicated for use in higher aesthetically required anterior regions of the oral cavity but are not restricted for that application.

CONTRAINDICATIONS: No known (reported) or anticipated contraindications in use of ceramic abutments when used with implants that have achieved integration in alveolar bone. 3i abutments are not indicated for use in locations other than alveolar ridges.

Implants/abutments should not be used in cases where remaining jawbone is too diminished to provide adequate width/height to surround implant. Lack of osseointegration or subsequent implant failure may occur in cases where there is insufficient available bone or poor bone quality, poor oral hygiene, heavy smoking or tobacco use or medical conditions such as blood disorders, infection(s), vascular impairment at surgical site, uncontrolled diabetes, heavy

smoking or tobacco abuse, drug or alcohol abuse, chronic high dose steroid therapy, medical conditions such as blood clotting disorders, current or ongoing anticoagulant therapy, metabolic bone disease or other metabolic or systemic disorders which may adversely affect bone or wound healing or cases in which the available bone is too diminished to provide adequate width or height to adequately hold implants and restorative appliances.

WARNINGS: For safe and effective use of 3i implants and abutments, it is strongly suggested that specialized training be undertaken since the surgical techniques required to place dental implants are highly specialized, complex procedures. Improper patient selection and technique can cause implant and/or abutment failure with possible loss of supporting bone. 3i implants are not indicated for use in sites other than alveolar ridges.

PRECAUTIONS: Thorough screening of prospective implant candidates must be performed. Visual inspection as well as panoramic and periapical radiographs are essential to determine anatomical landmarks, occlusal conditions, periodontal status, and adequacy of bone. Lateral cephalometric radiographs, CT scans and tomogram may also be beneficial.

ADVERSE EFFECTS: Ceramic abutments: No known (reported) or anticipated adverse effects.

Loss of implant anchorage (failure to integrate) and loss of the prosthesis are possible occurrences after surgery. Lack of quantity or quality of remaining bone, infections, poor patient oral hygiene or cooperation, and generalized diseases (diabetes, etc.) are some potential causes for loss of anchorage.

SURGICAL COMPLICATIONS: Ceramic abutments: No known (reported) or anticipated surgical complications. The implant procedure has risks, including localized swelling, dehiscence, tenderness of short duration, edema, hematoma, or bleeding. Numbness of the lower lip and chin region following lower jaw surgery, and of the tissue beside the nose following upper jaw surgery, is a possible side effect of the surgery. Though it would most probably be of a temporary nature, in very rare cases, the numbness has been permanent. Gingival/mucosal (gum tissue) ulceration, tissue reaction, or infection may occur, but generally responds to local care.

End Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 29 1999

Mr. William G. Conety
Implant Innovations, Incorporated
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

Re: K991947
Trade Name: 3I Ceramic Abutment System
Regulatory Class: III
Product Code: DZE
Dated: September 7, 1999
Received: September 8, 1999

Dear Mr. Conety:

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 (Premarket 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 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

510(k) Number: K

Device Name: Ceramic Abutment System

INDICATIONS FOR USE:

Ceramic abutments are indicated for use with endosseous dental implants, to extend the implant's coronal aspect through the mucosal tissues and into the oral cavity, for prosthetic attachment. Ceramic abutments are primarily indicated for use in the higher aesthetically required anterior regions of the oral cavity but are not restricted for that application.

DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K991947

Prescription Use: ✓ OR Over-the-Counter Use: _____ Per 21 CFR 801.109)