K051501

OCT 1 9 2005

XI. 510(k) SUMMARY

Submitter: Kyung-Bin Lee, Pres., Acucera, Inc., Namyangiu-si, Gyeonggi 472-861, (Seoul) Korea. Phone: 82 – (0)31-527-6940.

I. Classification Names and numbers: Endosseous dental implant abutment, code NHA,.

II. Common/Usual Name: Abutment, implant abutment

III. Proprietary Names: Zir Ace™

IV. Establishment Registration Number: Foreign, in process

V. Classification: These products have recently been classified by the Dental Products Panel into 21 CFR 872.3630, Class II.

VI. Device Description: ZirAce™ is a ceramic abutment composed of zirconium oxide stabilized with yttrium oxide, and containing niobium oxide and aluminum oxide to improve the properties and color. The zirconium oxide stabilized with yttrium oxide ceramic has been used for about 25 years as hip-implant and other prostheses and is capable of machining by modern CAD-CAM methods. Various versions of this ceramic have been cleared for dental uses as inlays, onlays and veneers by Dentronic in K971414 and for such materials and crowns and copings by Cynovad in K033227 and Medin Tech in K043472. The material is radio-opaque, for ready visualization.

VII. Substantial Equivalence: Zir Ace™ is substantially equivalent, and nearly identical, to the Procera Abutment Branemark, cleared in K042658. It is equivalent to several other ceramic abutments, such as the Esthetic Zirconia Abutment (K031719), the Astra Tech Dental Implants—Ceramic abutment (K023631) and others such as the Ceramic Abutment (K9132255), the Procera Abutment System (K974150), the 3i Dental Abutment (K032263), and the Sterngold ImplamMed Hex Implant (K081516). The material from which the Zir Ace™ abutment is manufactured is equivalent to the common yttrium stabilized zirconia used in Denzir cleared by Dentronic AB in K984201 and Cynovad Zircon (K023327). This has been demonstrated by extensive physical tests summarized in Appendix IV and provided from the literature in Appendix V.

The "510(k) "Substantial Equivalence" Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed as described below:

1. These products have the same intended use, to be cemented or screw-fastened to endosseous dental implants to provide a basis for building a prostheses to provide mastication in edentulous or partly edentulous persons.

(repl. p. 11)

2. The technological characteristics for this product are similar to those for the predicate devices and those currently on the market except for slight differences in composition. Physical properties, including compressive strength, fracture toughness, and durability have been thoroughly tested with physical tests and in accordance with ISO 14801 "Dynamic Continuous Fatigue Test." The biocompatibility of the material used has also been studied carefully; it has been found equivalent to the common tetragonal yttrium stabilized zirconia.

3. Descriptive information provided shows that the materials from which this device is made are well established in the more demanding areas of hip implants and that they have been more well recognized for their broad use in dental structures.

4. The FDA "Decision-Making Process" chart was used and appears in Appendix V.1.

(End of Summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 19 2005

Mr. Kyung-Bin Lee
President
Acucera, Incorporated
Namyangju-si,
Gyeonggi
Seoul
REPUBLIC OF KOREA 472-861

Re: K051501
Trade/Device Name: ABUTMENT, IMPLANT ABUTMENT
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous dental implant abutment
Regulatory Class: II
Product Code: NHA
Dated: September 30, 2005
Received: October 3, 2005

Dear Mr. Lee:

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 application (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 such 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 begin 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/industry/support/index.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

VIII.1 Indications for Use: [Separate Page]

510(k) Number: K051501

Device Name: Zir Ace™ ceramic abutment

Indications for use:

ZirAce™ abutments are indicated for use in partially edentulous patients requiring prosthetic devices and/or endosseous implants to restore chewing function. They are especially applicable to anterior or canine teeth where the typical titanium color may show through the gum. In addition to the Branemark (Nobel Biocare) implants, the ZirAce™ abutments hexagon connector fits the external hexagon of the following implants:

- 3i ,
- Lifecore Biomedical ,
- Sterngold Implamed.

Prescription Use __X__ (Per 21 CFR 801 Subpart D)

OR

Over-The-Counter Use ___ (21 Part 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K051501