JUL 12 2005 K051011

VII. SECTION 10 - 510(K) SUMMARY

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR Part 807.92.

1. **Applicant's Name and Address**

Atlantis Components Inc.
25 First Street
Cambridge, Massachusetts 02141
Telephone Number: 617-661-9799
Fax Number: 617-661-9063
Contact Person: Franklin Uyleman
Manager of Quality and Regulatory Affairs

2. **Name of Device**

Trade Name: Atlantis™ Abutment for 3i Certain™ Implant
Common Name: Endosseous dental implant abutment
Classification Name: Endosseous dental implant abutment
21 CFR 872.3630 Product code NHA

3. **Legally Marketed Device to which Equivalence is claimed (Predicate Device)**

Manufacturer	Device	510(k) Number
Atlantis Components Inc.	Atlantis Abutment and Abutment Screw	K981858

4. **Description of the Device**

The devices covered in this submission are abutments which are placed into the dental implant to provide support for a prosthetic restoration. The subject abutments are indicated for cemented restorations.

4. Description of the Device (continued)

The **Atlantis™ Abutments for 3i Certain™ Implant** and abutment screws are made from Titanium grade Ti-6Al-4V ELI (Meets ASTM Standard F-136). The abutment is placed over the implant shoulder and is mounted into the implant with a screw. The abutments are compatible with 3i Certain Standard Implants with 4.1mm, 5.0mm, 6.0mm diameters; the OSSEOTITE® XP Certain Implants with 5.0mm and 6.0mm diameters; and the OSSEOTITE® NT® Certain™ Implants with 4.0mm, 5.0mm and 6.0mm diameters.

5. Intended Use of the Device

The devices covered by this submission are abutments which are placed into a dental implant to provide support for a prosthetic reconstruction. The Atlantis Abutment is intended for use as an accessory to an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.

6. Basis for Substantial Equivalence

The **Atlantis™ Abutments for 3i Certain Implants** are substantially equivalent in intended use, material, design and performance to the Atlantis Abutments cleared under K981858.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2005

Atlantis Components, Incorporated
C/O Betsy A. Brown
B.A. Brown & Associates
8944 Tamaroa Terrace
Skokie, Illinois 60076

Re: K051011
Trade/Device Name: Atlantis™ Abutment for 3i Certain™ Implant
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: April 20, 2005
Received: April 21, 2005

Dear Ms. Brown:

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

Indications for Use

510(k) Number (if Known) K051011

Device Name: Atlantis ™ Abutment for 3i Certain™ Implant

Indication for Use:

The Atlantis Abutment is intended for use as an accessory to an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 SubpartD) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

R Beth DVS for Dr S. Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K051011