

3/22/99

K981858

## 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

- Submitted by: Atlantis Components, Inc.  
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Cambridge, MA 02142-1112  
617-661-9799  
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[info@atlantiscomp.com](mailto:info@atlantiscomp.com)
- Contact Person: Andrew Ziegler, Chief Technology Officer
- Device Name: Atlantis Abutment System  
Classification Name: Class III Endosseous Implants per 21 C.F.R. 872.3640
- Equivalent Device: Lifecore Biomedical RD Hexed UCLA Abutment Gold Sleeve and Lifecore Biomedical RD Titanium UCLA Abutment Screw With .048 in Hex. (These are covered in one or more of the following: K931468, K944069.)
- Device Description: The Atlantis abutment is an abutment used with an endosseous implant that is implanted in the upper or lower jawbone. The abutment sits on the implant interface and is retained by the Atlantis screw. The abutment allows the option for the prostheses to be cemented directly to the abutment, or to be retained by a screw. The abutment is ordered by prescription from a Dentist, then is designed and manufactured by Atlantis to that prescription.
- Intended 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 prostheses, in the mandible or maxilla. The prostheses can be screw or cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. The impression coping is intended to transfer the position of the implant in the oral cavity to a working cast. The impression coping screw is intended to temporarily secure the impression coping to either the implant fixture or the analog fixture.
- Comparison of Technological Characteristics: The technological characteristics of the Atlantis Abutment System and the corresponding predicate Lifecore UCLA abutment are identical.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 22 1999

Mr. Andrew Ziegler  
Chief Technology Officer  
Atlantis Components, Incorporated  
270 Third Street  
Cambridge, Massachusetts 02142-1112

Re: K981858  
Trade Name: Atlantis Abutment and Atlantis Abutment  
Screw  
Regulatory Class: III  
Product Code: DZE  
Dated: December 21, 1998  
Received: December 22, 1998

Dear Mr. Ziegler

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 (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 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 pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of

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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" (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

LABELING AND INSTRUCTIONS:

DEVICE NAME: ATLANTIS ABUTMENT SYSTEM

INDICATIONS FOR USE

The Atlantis Abutment is used to connect an implanted fixture to a restoration.

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Concurrence of CDRH, Office of Device Evaluation (ODE)  
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Prescription Use   
(Per 21 CFR 801.109)

Over-The-Counter Use

Sina Pinar  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K981858