K103234

JUN 30 2011

510(k) Summary

GC AADVA TI ABUTMENTS – BO AC SV BH

Date Prepared: June 10, 2011

Submitter/Contact Person	H. Carl Jenkins The **Wood Burditt** Group FDA Regulatory Counseling 10 E. Scranton Avenue, Suite 201 Lake Bluff, IL 60044 (ph) (847) 234-7500 x 205 (fax) (847) 574-0728 (email) hcjenkins@woodburditt.com
Applicant	GC America, Inc. 3737 W. 127th Street Alsip, IL 60803 800.323.3386 x4042 708.897.4042 708.897.4031 (fax)
Manufacturer	GC CORPORATION. 76−1 HASUNUMA−CHO, ITABASHI−KU TOKYO 174−8585 JAPAN
Device Name	GC AADVA TI ABUTMENTS – BO AC SV BH
Common Name	Endosseous Dental Implant Abutment
Classification	Class II Procode NHA Regulation: 21 CFR 872.3630

Device Description

The "GC Aadva Ti Abutments – Bo Ac Sv Bh" are abutments which are placed into a dental implant to provide support for a prosthetic restoration. The subject abutments are indicated for use with the following implant fixtures:

Types	Material	Antirotational Features	Engaged Fixture (Manufacturer)
IN-Bo-3.3mm #354	Ti-6Al-4V	Internal Square	Φ3.3 Bone Level Implant NC (Institut straumann AG)
IN-Bo-4.1mm #355	Ti-6Al-4V	Internal Square	Φ4.1, Φ4.8 Bone Level Implant RC (Institut straumann AG)
IN-Ac-3.5mm #356	Ti-6Al-4V	Internal Hexagon	Φ3.5 NobelActive NP (Nobel Biocare AB)
IN-Ac-4.3mm #357	Ti-6Al-4V	Internal Hexagon	Φ4.3, Φ5.0 NobelActive RP (Nobel Biocare AB)
IN-Bh-3.8mm #358	Ti-6Al-4V	Internal Hexagon	Φ3.8mm Tapered Internal Implant (BioHorizons)
IN-Bh-4.6mm #359	Ti-6Al-4V	Internal Hexagon	Φ4.6mm Tapered Internal Implant (BioHorizons)
IN-Bh-5.8mm #360	Ti-6Al-4V	Internal Hexagon	Φ5.8mm Tapered Internal Implant (BioHorizons)
IN-Sv-3.5mm #351	Ti-6Al-4V	Internal Hexagon	Φ3.7, Φ4.1 Tapered Screw-Vent (Zimmmer)
IN-Sv-4.5mm #352	Ti-6Al-4V	Internal Hexagon	Φ4.7 Tapered Screw-Vent (Zimmmer)
IN-Sv-5.7mm #353	Ti-6Al-4V	Internal Hexagon	Φ6.0 Tapered Screw-Vent (Zimmmer)

The "GC Aadva Ti Abutments – Bo Ac Sv Bh" components are made of Titanium grade Ti-6Al-4V and meets the requirements of ISO : 5832-3. The abutments are mounted into the implant

with a screw also made of Titanium grade Ti-6Al-4V, which meets the requirements of ISO : 5832-3. Each of these abutments have the following design limitations:

Collar	Angulation	Length	Width	Head space
Max.6.0mm Min.2.5mm	Max.20° Min.0°	Max.12.0mm Min.2.5mm - 3.5mm (depending on abutment selected)	Max.Φ11.6mm Min.Φ4.1mm - Φ 6.1mm (depending on abutment selected	Max.11.8mm Min.1.0mm

Intended Use:

The "GC Aadva Ti Abutments – Bo Ac Sv Bh" is intended for use with an endossous dental implant to support a prosthetic device in a partially or completely endentulous patient. It is intended for use to support a tooth prosthesis, in the mandible or maxilla. The abutment screw is intended to secure the abutment to the endosseous dental implant.

Indications for use:

Indications for Use: **"GC AADVA TI ABUTMENTS – BO AC SV BH"** are dental implant abutments for use with partially or fully edentulous patients to restore chewing function by attachment to a dental implant fixture placed in the maxilla or mandible. Each abutment is accompanied by a screw in order to engage corresponding dental implant fixture.

Abutment – Implant Compatibility Table

Abutment	Material	Antirotational Features	Implant -- Engaged Fixture (Manufacturer)
IN-Bo-3.3mm #354	Ti-6Al-4V	Internal Square	Φ3.3 Bone Level Implant NC (Institut straumann AG)
IN-Bo-4.1mm #355	Ti-6Al-4V	Internal Square	Φ4.1, Φ4.8 Bone Level Implant RC (Institut straumann AG)
IN-Ac-3.5mm #356	Ti-6Al-4V	Internal Hexagon	Φ3.5 NobelActive NP (Nobel Biocare AB)
IN-Ac-4.3mm #357	Ti-6Al-4V	Internal Hexagon	Φ4.3, Φ5.0 NobelActive RP (Nobel Biocare AB)

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IN-Bh-3.8mm #358	Ti-6Al-4V	Internal Hexagon	Φ3.8mm Tapered Internal Implant (BioHorizons)
IN-Bh-4.6mm #359	Ti-6Al-4V	Internal Hexagon	Φ4.6mm Tapered Internal Implant (BioHorizons)
IN-Bh-5.8mm #360	Ti-6Al-4V	Internal Hexagon	Φ5.8mm Tapered Internal Implant (BioHorizons)
IN-Sv-3.5mm #351	Ti-6Al-4V	Internal Hexagon	Φ3.7, Φ4.1 Tapered Screw-Vent (Zimmmer)
IN-Sv-4.5mm #352	Ti-6Al-4V	Internal Hexagon	Φ4.7 Tapered Screw-Vent (Zimmmer)
IN-Sv-5.7mm #353	Ti-6Al-4V	Internal Hexagon	Φ6.0 Tapered Screw-Vent (Zimmmer)

Prescription Use Only.

Substantial Equivalence:

The applicant device is substantially equivalent to the predicate devices in its intended use, indications for use, and design, as described below:

Predicate Devices

Product	Manufacturer	K Number
Atlantis Straumann Bone Level Abutment	Astra Tech Inc. 25 First Street Cambridge, Massachusetts 02141 USA	K083871
NobelActive Internal Connection	Nobel Biocare USA, LLC. 22715 Savi Ranch Parkway, Yorba Londa CA 92887 USA	K071370
GC Aadva Abutment	GC Corporation 76-1 Hasunuma-Cho, Itabashi-Ku Tokyo, Japan	K072100
Atlantis Abutment for BioHorizons Implant	Atlantis Components Inc. 25 First Street Cambridge, Massachusetts 02141 USA	K073258
ATLANTIS ABUTMENT FOR ZIMMER INTERFACE	Atlantis Components, INC. 8944 Tamaroa Terrace Skokie, IL 60076	K053373

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Materials used in blocks and screws

Component	Applicant Device Materials	Predicate Devices that Use Same Materials
Block	**Ti-6Al-4V** ISO : 5832-3 Ti : Bal. Al : 5.5~6.75 V : 3.5~4.5 Fe<0.3 O<0.2 C<0.08 N<0.05 H<0.015	Atlantis Straumann Bone Level Abutment (K083871) NobelActive Internal Connection (K071370) GC AADVA ABUTMENT (K072100) Atlantis Abutment for BioHorizons Implant (K073258) ATLANTIS ABUTMENT FOR ZIMMER INTERFACE (K053373)
Screw	**Ti−6Al−4V** ISO : 5832-3 Ti : Bal. Al : 5.5~6.75 V : 3.5~4.5 Fe<0.3 O<0.2 C<0.08 N<0.05 H<0.015	Atlantis Straumann Bone Level Abutment (K083871) NobelActive Internal Connection (K071370) NobelActive Zirconia Abutment (K072129) GC AADVA ABUTMENT (K072100) Atlantis Abutment for BioHorizons Implant (K073258) ATLANTIS ABUTMENT FOR ZIMMER INTERFACE (K053373)

Technological Characteristic	Applicant Device	Predicate Devices
Material	**Ti−6Al−4V** ISO : 5832-3	**Ti−6Al−4V** ISO : 5832-3
Performance Characteristics	Allows the prosthesis to be retained to the abutment; abutment screw is intended to secure the abutment to the endosseous dental implant.	Allows the prosthesis to be retained to the abutment; abutment screw is intended to secure the abutment to the endosseous dental implant.
Intended Use	Intended for use with an endosseous dental implant to support a prosthetic device in a partially or fully endentulous patient to restore chewing	Intended for use with an endosseous dental implant to support a prosthetic device in a partially or fully endentulous patient to restore chewing

	function. Intended to be attached to a dental implant fixture placed in the maxilla or mandible.	function. Intended to be attached to a dental implant fixture placed in the maxilla or mandible.

Summary of Non-Clinical Performance Testing:

Static and fatigue testing was conducted on the "worst case scenario" implant-abutment combination assemblies in accordance with FDA's Guidance Document for Dental Implants and ISO 14801. Test results demonstrated that the "GC Aadva Ti Abutments – Bo Ac Sv Bh" are compatible with the referenced implant fixtures and the implant-abutment assemblies support adequate static and fatigue test loads. Performance testing demonstrates that the device performs as intended and is as safe and effective as the cited predicates.

Substantial Equivalence Conclusion Statement:

Based on noted similarities and comparative traits in the indications for use, manufacturing materials, design and performance characteristics, and the fact that the applicant device and the predicate devices have demonstrated acceptable static and fatigue test loads during performance testing conducted in accordance with FDA's Guidance Document for Dental Implants and ISO 14801, the "GC Aadva Ti Abutments – Bo Ac Sv Bh" is substantially equivalent to the following predicate devices:

Product	Manufacturer	K Number
Atlantis Straumann Bone Level Abutment	Astra Tech Inc. 25 First Street Cambridge, Massachusetts 02141 USA	K083871
NobelActive Internal Connection	Nobel Biocare USA, LLC. 22715 Savi Ranch Parkway, Yorba Londa CA 92887 USA	K071370
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room --WO66-G609
Silver Spring, MD 20993-0002

GC America, Incorporated
C/O Mr. H. Carl Jenkins
Wood Burditt Group
10 East Scranton Avenue, Suite 201
Lake Bluff, Illinois 60044

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Re: K103234
Trade/Device Name: GC AADVA TI ABUTMENTS - BO AC SV BH
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: June 10, 2011
Received: June 13, 2011

Dear Mr. Jenkins:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 5 – Indications for Use Statement

Indications for Use

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K103234

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)