K113816

Section 6 – 510(k) Summary

JAN 30 2013

**510(k) Summary for GC Aadva™ Abutments – Zirconia – Bo Ac Bh Sv**

***510(k) Summary***

## GC Aadva™ Abutments – Zirconia – Bo Ac Bh Sv

Date Prepared: October 18, 2012

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

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**Device Description**

The "GC Aadva™ Abutments – Zirconia – Bo Ac Bh Sv" 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:

Abutment - Implant Compatibility Table

| Types | Material | Antirotational Features | Implant - Engaged Fixture (Manufacturer) |
|---|---|---|---|
| IN-Bo-3.3mm #154 | Zirconia : Y-TZP | Internal Square | Φ3.3<br>Bone Level Implant NC<br>(Institut straumann AG)<br>K062129 |
| IN-Bo-4.1mm #155 | Zirconia : Y-TZP | Internal Square | Φ4.1, Φ4.8<br>Bone Level Implant RC<br>(Institut straumann AG)<br>K062129 |
| IN-Ac-3.5mm #156 | Zirconia : Y-TZP | Internal Hexagon | Φ3.5<br>NobelActive NP<br>(Nobel Biocare AB)<br>K071370 |
| IN-Ac-4.3mm #157 | Zirconia : Y-TZP | Internal Hexagon | Φ4.3, Φ5.0<br>NobelActive RP<br>(Nobel Biocare AB)<br>K071370 |
| IN-Bh-3.8mm #158 | Zirconia : Y-TZP | Internal Hexagon | Φ3.8<br>Tapered Internal Implant<br>(BioHorizons)<br>K071638 |
| IN-Bh-4.6mm #159 | Zirconia : Y-TZP | Internal Hexagon | Φ4.6<br>Tapered Internal Implant<br>(BioHorizons)<br>K071638 |
| IN-Sv-3.5mm #151 | Zirconia : Y-TZP | Internal Hexagon | Φ3.7, Φ4.1<br>Tapered Screw-Vent<br>(Zimmer Dental Inc.)<br>K013227 |
| IN Sv-4.5mm #152 | Zirconia : Y-TZP | Internal Hexagon | Φ4.7<br>Tapered Screw-Vent<br>(Zimmer Dental Inc.)<br>K013227 |

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The "GC Aadva™ Abutments – Zirconia – Bo Ac Bh Sv" abutment components comply with ISO 13356:2008 – Implants for Surgery – Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP). The abutments are mounted into the implant with a screw made of Titanium grade Ti-6Al-4V, which meets the requirements of ISO : 5832-3. Each of these abutments have the following design limitations:

| Types | Collar | Post | Angulation | Length | Width | Head space |
|---|---|---|---|---|---|---|
| IN-Bo-3.3mm #154 | Max.6.0mm | Max.10.0mm | Max.20° | Max.12.5mm | Max. Ø 11.6mm | Max.11.8mm |
| | Min.2.5mm | Min.4.0mm | Min.0° | Min.6.5mm | Min. Ø 4.1mm | Min.1.0mm |
| IN-Bo-4.1mm #155 | Max.6.0mm | Max.10.0mm | Max.20° | Max.12.5mm | Max. Ø 11.6mm | Max.11.8mm |
| | Min.2.5mm | Min.4.0mm | Min.0° | Min.6.5mm | Min. Ø 4.9mm | Min.1.0mm |
| IN-Ac-3.5mm #156 | Max.6.0mm | Max.10.0mm | Max.20° | Max.12.5mm | Max. Ø 11.6mm | Max.11.8mm |
| | Min.2.5mm | Min.4.0mm | Min.0° | Min.6.5mm | Min. Ø 4.1mm | Min.1.0mm |
| IN-Ac-4.3mm #157 | Max.6.0mm | Max.10.0mm | Max.20° | Max.12.5mm | Max. Ø 11.6mm | Max.11.8mm |
| | Min.2.5mm | Min.4.0mm | Min.0° | Min.6.5mm | Min. Ø 4.9mm | Min.1.0mm |
| IN-Bh-3.8mm #158 | Max.6.0mm | Max.10.0mm | Max.20° | Max.12.5mm | Max. Ø 11.6mm | Max.11.8mm |
| | Min.2.5mm | Min.4.0mm | Min.0° | Min.6.5mm | Min. Ø 4.1mm | Min.1.0mm |
| IN-Bh-4.6mm #159 | Max.6.0mm | Max.10.0mm | Max.20° | Max.12.5mm | Max. Ø 11.6mm | Max.11.8mm |
| | Min.2.5mm | Min.4.0mm | Min.0° | Min.6.5mm | Min. Ø 4.9mm | Min.1.0mm |
| IN-Sv-3.5mm #151 | Max.6.0mm | Max.10.0mm | Max.20° | Max.12.5mm | Max. Ø 11.6mm | Max.11.8mm |
| | Min.2.5mm | Min.4.0mm | Min.0° | Min.6.5mm | Min. Ø 4.1mm | Min.1.0mm |
| IN-Sv-4.5mm #152 | Max.6.0mm | Max.10.0mm | Max.20° | Max.12.5mm | Max. Ø 11.6mm | Max.11.8mm |
| | Min.2.5mm | Min.4.0mm | Min.0° | Min.6.5mm | Min. Ø 4.9mm | Min.1.0mm |

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**Intended Use:**

The "GC Aadva™ Abutments – Zirconia – Bo Ac Bh Sv" 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™ Abutments – Zirconia – Bo Ac Bh Sv** 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

| Types | Material | Antirotational Features | Implant - Engaged Fixture (Manufacturer) |
|---|---|---|---|
| IN-Bo-3.3mm #154 | Zirconia : Y-TZP | Internal Square | Φ3.3<br>Bone Level Implant NC<br>(Institut straumann AG)<br>K062129 |
| IN-Bo-4.1mm #155 | Zirconia : Y-TZP | Internal Square | Φ4.1, Φ4.8<br>Bone Level Implant RC<br>(Institut straumann AG)<br>K062129 |
| IN-Ac-3.5mm #156 | Zirconia : Y-TZP | Internal Hexagon | Φ3.5<br>NobelActive NP<br>(Nobel Biocare AB)<br>K071370 |

| | | | |
|---|---|---|---|
| IN-Ac-4.3mm #157 | Zirconia : Y-TZP | Internal Hexagon | Φ4.3, Φ5.0<br>NobelActive RP<br>(Nobel Biocare AB)<br>K071370 |
| IN-Bh-3.8mm #158 | Zirconia : Y-TZP | Internal Hexagon | Φ3.8<br>Tapered Internal Implant<br>(BioHorizons)<br>K071638 |
| IN-Bh-4.6mm #159 | Zirconia : Y-TZP | Internal Hexagon | Φ4.6<br>Tapered Internal Implant<br>(BioHorizons)<br>K071638 |
| IN-Sv-3.5mm #151 | Zirconia : Y-TZP | Internal Hexagon | Φ3.7, Φ4.1<br>Tapered Screw-Vent<br>(Zimmer Dental Inc.)<br>K013227 |
| IN Sv-4.5mm #152 | Zirconia : Y-TZP | Internal Hexagon | Φ4.7<br>Tapered Screw-Vent<br>(Zimmer Dental Inc.)<br>K013227 |

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 list

| Product | Manufacturer | K Number |
|---|---|---|
| Atlantis Straumann Bone Level Abutment | Astra Tech Inc.<br>25 First Street Cambridge, Massachusetts | K083871 |

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| | | |
|---|---|---|
| | 02141 USA | |
| NobelActive Zirconia Abutment | Nobel Biocare USA, LLC.<br>22715 Savi Ranch Parkway, Yorba Londa<br>CA 92887 USA | K072129 |
| GC Aadva Abutment | GC Corporation<br>76-1 Hasunuma-Cho, Itabashi-Ku<br>Tokyo, Japan | K072100 |
| Atlantis Abutment in Zirconia for BioHorizons Implant | Atlantis Components Inc.<br>25 First Street Cambridge, Massachusetts<br>02141 USA | K073540 |
| Atlantis Abutment for BioHorizons Implant | Atlantis Components Inc.<br>25 First Street Cambridge, Massachusetts<br>02141 USA | K073258 |
| ATLANTIS ABUTMENT FOR ZIMMER INTERFACE | Astra Tech Inc.<br>25 First Street Cambridge, Massachusetts<br>02141 USA | K053373 |

Materials used in blocks and screws

| Component | Material | Predicate devices using same materials specified here |
|---|---|---|
| Block | **Zirconia : Y-TZP**<br>ISO : 13356<br><br>ZrO2+HfO2+Y2O3 > 99.0<br>Y2O3 : 4.5~5.4<br>Hf2O3<5 | Atlantis Straumann Bone Level Abutment (K083871)<br><br>NobelActive Zirconia Abutment (K072129)<br><br>GC AADVA ABUTMENT (K072100) |

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| | | |
|---|---|---|
| | Al2O3<0.5<br>Other oxides<0.5 | Atlantis abutment in zirconia for 3i certain interface (K063734)<br><br>Atlantis Abutment in Zirconia for BioHorizons Implant (K073540)<br><br>ATLANTIS ABUTMENT FOR ZIMMER INTERFACE (K053373) |
| Screw | **Ti−6Al−4V**<br>ISO : 5832-3<br><br>Ti : Bal.<br>Al : 5.5~6.75<br>V : 3.5~4.5<br>Fe<0.3<br>O<0.2<br>C<0.08<br>N<0.05<br>H<0.015 | Atlantis Straumann Bone Level Abutment (K083871)<br><br>NobelActive Internal Connection (K071370)<br><br>GC AADVA ABUTMENT (K072100)<br><br>Atlantis Abutment in Zirconia for BioHorizons Implant (K073540)<br><br>Atlantis Abutment for BioHorizons Implant (K073258)<br><br>ATLANTIS ABUTMENT FOR ZIMMER INTERFACE (K053373) |

| Technological Characteristic | Applicant Device | Predicate Devices |
|---|---|---|
| Material | **Zirconia : Y-TZP**<br>ISO : 13356 | **Zirconia : Y-TZP**<br>ISO : 13356 |
| Performance Characteristics | Allows the prosthesis to be retained to the abutment; abutment screw is intended to | Allows the prosthesis to be retained to the abutment; abutment screw is intended to |

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| | | |
|---|---|---|
| | secure the abutment to the endosseous dental implant. | 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 function. Intended to be attached to a dental implant fixture placed in the maxilla or mandible. | 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. |

**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™ Abutments – Zirconia – Bo Ac Bh Sv" 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™ Abutments – Zirconia – Bo Ac Bh Sv" is substantially equivalent to the following predicate devices:

| Product | Manufacturer | K Number |
|---|---|---|
| Atlantis Straumann Bone Level Abutment | Astra Tech Inc.<br>25 First Street Cambridge, Massachusetts 02141 USA | K083871 |
| NobelActive Zirconia Abutment | Nobel Biocare USA, LLC.<br>22715 Savi Ranch Parkway, Yorba Londa CA 92887 USA | K072129 |
| GC Aadva Abutment | GC Corporation<br>76-1 Hasunuma-Cho, Itabashi-Ku<br>Tokyo, Japan | K072100 |

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| | | |
|---|---|---|
| Atlantis Abutment in Zirconia for BioHorizons Implant | Atlantis Components Inc.<br>25 First Street Cambridge, Massachusetts<br>02141 USA | K073540 |
| Atlantis Abutment for BioHorizons Implant | Atlantis Components Inc.<br>25 First Street Cambridge, Massachusetts<br>02141 USA | K073258 |
| ATLANTIS ABUTMENT FOR ZIMMER INTERFACE | Astra Tech Inc.<br>25 First Street Cambridge, Massachusetts<br>02141 USA | K053373 |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 30, 2013

GC America, Incorporated
C/O Mr. Carl H. Jenkins
The Wood Burditt Group
10 East Scranton Avenue, Suite 201
LAKE BLUFF IL 60044

Re: K113816
Trade/Device Name: GC AadvaTM Abutments – Zirconia – Bo Ac Bh Sv
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: January 17, 2013
Received: January 25, 2013

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.

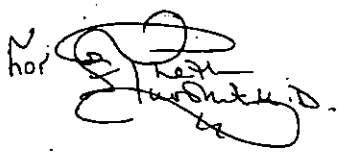
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



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

Enclosure

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Section 5 – Indications for Use Statement

**Indications for Use**

**510(k) Number (if known):** K113816

**Device Name:** GC Aadva™ Abutments – Zirconia – Bo Ac Bh Sv

**Indications for Use:** **GC Aadva™ Abutments –Zirconia – Bo Ac Bh Sv** 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.

(Cont'd on next page)

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA 2013.01.30 08:08:47 -05'00'

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

**510(k) Number:** K113816

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## Indications for Use

**510(k) Number (if known):** K113816

**Device Name:** GC Aadva™ Abutments – Zirconia – Bo Ac Bh Sv

(Cont'd from previous page)

Abutment – Implant Compatibility Table

| Types | Material | Antirotational Features | Implant - Engaged Fixture (Manufacturer) |
|---|---|---|---|
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| IN-Bh-3.8mm #158 | Zirconia : Y-TZP | Internal Hexagon | Φ3.8<br>Tapered Internal Implant<br>(BioHorizons)<br>K071638 |
| IN-Bh-4.6mm #159 | Zirconia : Y-TZP | Internal Hexagon | Φ4.6<br>Tapered Internal Implant<br>(BioHorizons)<br>K071638 |
| IN-Sv-3.5mm #151 | Zirconia : Y-TZP | Internal Hexagon | Φ3.7, Φ4.1<br>Tapered Screw-Vent<br>(Zimmer Dental Inc.)<br>K013227 |
| IN Sv-4.5mm #152 | Zirconia : Y-TZP | Internal Hexagon | Φ4.7<br>Tapered Screw-Vent<br>(Zimmer Dental Inc.)<br>K013227 |