K101068

Berkeley Implant™ Precision Implant Technology

342 Raritan Center Parkway, Edison, New Jersey 08837 Phone: 732-346-1000 Fax: 732-875-1169

VI. 510(K) Summary

AUG 2 3 2010

Company Name:	Radiant Express LLC DBA: Berkeley Implant
Address:	342 Raritan Center Parkway Edison, NJ 08837
Telephone Number:	(732) 346-1000
Fax Number:	(732) 875-1169
Estab. Registration Number:	K101068
Owner/Operator Number:	9087046
Submitter's Name:	Ryan Chiou
Contact Person:	Ryan Chiou
Date Summary Prepared:	April 10, 2010
Classification Name:	Abutment, Implant, Dental, Endosseous
Common/Usual Name:	Endosseous dental implant abutment
Device Trade Name:	AccuFit™ Dental Implant Abutments & Screws
Predicate Devices:	See tables B & C below

1. Description:

The *AccuFit™* Dental Abutments and Screws are designed for use with commercially available dental implant systems. The abutments will seat directly on implants and are secured by screws to become sub-structure of prosthesis. These abutments are offered in a straight body with a straight or scalloped prosthetic margin and are made of Titanium alloy Ti6AlV4.

A list of dental implant systems, which the *AccuFit™* family of products is compatible with, is shown in tables within this document. The abutments and screws of the compatible systems are listed as the predicates for this filing.

The *AccuFit™* Abutment System is compatible with the commercial implant manufacturer's (Table A) bone-level implant bodies and has mating diameters, lead-in bevels, internal/external hex sizes, and internal threads. Abutments and screws are designed to be compatible with each of the following implant systems and sizes:

Table A. Compatible Commercial Implant Manufacturers

Implant Company	Implant System	Implant Platform Diameter
Zimmer Dental	Tapered Screw-vent	3.5, 4.5, 5.7 mm
Nobel-Biocare	NobelReplace Select	3.5, 4.3, 5.0 mm
Biomet 3i	Osseotite Certain	3.4, 4.1, 5.0 mm
Lifecore Biomedical	Renova (internal hex) Restore (external hex)	3.5, 4.5 mm 3.3, 4.1, 5.0 mm

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2. Intended Use:

AccuFit™ Abutments and screws are intended to attach to an endosseous dental implant and provide support and retention for a single tooth and multiple teeth restoration in the mandible or maxilla.

AccuFit™ Screws are intended for securing a abutment onto an endosseous dental implant.

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3. Technological Characteristics:

The *AccuFit*™ abutments and screws are made of Titanium alloy Ti6Al4V using the same fabrication procedures as those of the predicate devices. The Titanium alloy used conforms to the following standard:

Standard	Description
ASTM F136-08e1	**Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)**

4. Comparison Analysis:

The overall designs and technological characteristics of the *AccuFit*™ Abutment System are similar to that of the predicate devices. The materials used to manufacture the products and the indications for use are identical to the predicate devices.

To ensure compatibility, the following process is carried out:

- The commercially available implant components are purchased as samples.

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- The samples are measured using high-precision optical equipments, and the products are machined using equipments capable of precision of μm.
- As a quality control step, the components produced are cross-assembled with the commercially acquired samples. Screws are tightened to the amount of torque specified by the implant manufacturer. The interface between the components is then rechecked using the optical equipment to make sure precision fit is achieved.

Berkeley Implant monitors the compatible implants for modifications to ensure future compatibility. In the event of any modification by the original manufacturers, Berkeley Implant will either modify the *AccuFit™* abutment to ensure compatibility, or cease claiming compatibility to the modified implants.

The tables below summarize *AccuFit™* Abutments & Screws and the predicate devices' K numbers.

Table B: AccuFit™ Preformed Stock Abutments and Predicate Devices' K-numbers

AccuFit Device	Predicate Device	K# for Predicate	Material
Preformed, stock Titanium Abutments & Screws	Zimmer Tapered Screw-vent Hex-lock abutments & screws	K061410, K011028	Same as predicate devices: • Abutment - Titanium Alloy Ti6Al4V • Screw - Titanium Alloy Ti6Al4V
	Nobel-Biocare NobelReplace Select Abutments and Screws	K021584	
	Biomet 3i GingiHue Post & Screw	K072642, K063403	
	Lifecore Renova & Restore Abutments	K032774, K965135	
	Diamodent Compatible Abutments	K034022, K010619, K993129	

While some of the predicate devices use sterilized packaging and some do not, the AccuFit™ abutments use non-sterile packaging and provide detailed instructions on sterilizing procedures.

5. CONCLUSION

The evaluation of the AccuFit™ Abutment System does not raise any additional concerns regarding safety and effectiveness and therefore is considered substantially equivalent to the predicate device.

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

Mr. Ryan Chiou
President
Radiant Express LLC
342 Raritan Center Parkway
Edison, New Jersey 08837

AUG 2 3 2010

Re: K101068
Trade/Device Name: AccuFit™ Dental Implant Abutments and Screws
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: August 5, 2010
Received: August 9, 2010

Dear Mr. Chiou:

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

K101068

V. Statement of Indications for Use

510(k) Number (if known): K101068

Device Name: *AccuFit*™ Dental Implant Abutments and Screws

Indications For Use:

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Prescription Use __X__ **AND/OR** **Over-The-Counter Use _____**

(Part 21 CFR 801 Subpart D) **(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)

Kevin Mulay for MSN

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

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