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

March 14, 2016

Allied Dental Solutions
Mr. Peter Zhou
President
1170 Centre Drive #I
City of Industry, California 91789

Re: K152845
Trade/Device Name: Allied Biocompat Abutment for Nobel Replace Interface
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: February 2, 2016
Received: February 9, 2016

Dear Mr. Zhou:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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 Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K152845

Device Name
Allied Biocompat Abutment for Nobel Replace Interface

Indications for Use *(Describe)*
The Allied Biocompat abutment is intended for use with 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 prosthesis can be cemented or screw retained to the abutment. The abutment screw is intended to secure the Allied Dental Solutions abutment to the endosseous implant.

Allied Biocompat Abutments are compatible with the following

Implant Manufacturer: Nobel Biocare

Implant Line: Replace Select Straight and Select Straight One Stage, Replace Select Tapered and Select Tapered One Stage

Implant Diameters: 3.5 (NP), 4.0 (RP), 5.0 (WP) and 6.0

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510k Summary
March 11, 2016
Allied Biocompat Abutments for Nobel Replace Interface

Name and address:
Allied Dental Solutions
Peter Zhou
1170 Centre Drive #I
City of Industry, California 91789
(909) 598-8036
www.allieddentalsolutions.com

Name of device: Allied Biocompat Abutments for Nobel Replace Interface
Classification Name: Endosseous dental implant abutment
CFR: 21 CFR 872.3630
Product Code: NHA

Device Description: Allied Biocompat patient-specific abutments are made from Ti-6Al-4V ELI which meets ASTM F136. Two abutment screw designs are included because the standard one does not fit the narrowest platform. The abutment is placed over the shoulder of the implant and fastened with the appropriate abutment screw. The patient-specific abutments designs share the same internal tri-lobe prosthetic interface but there are different implant platform diameters so there are 4 different diameters of abutment. The maximum angulation which can be ordered is 25°.

Allied Biocompat NB internal tri-lobe 3.5mm
Allied Biocompat NB internal tri-lobe 4.0mm
Allied Biocompat NB internal tri-lobe 5.0mm
Allied Biocompat NB internal tri-lobe 6.0mm

These are patient-specific CAD/CAM abutments designed and fabricated under the manufacturing control of Allied Dental Solutions.

Indications for Use: The Allied Biocompat abutment is intended for use with 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 prosthesis can be cemented or screw retained to the abutment. The abutment screw is intended to secure the Allied Dental Solutions abutment to the endosseous implant.

Allied Biocompat Abutments are compatible with the following

Implant Manufacturer: Nobel Biocare

Implant Line: Replace Select Straight and Select Straight One Stage, Replace Select Tapered and Select Tapered One Stage

Implant Diameters: 3.5 (NP), 4.0 (RP), 5.0 (WP) and 6.0

Testing Summary: Fit analysis (reverse engineering compatibility) to determine the abutments will fit the interfaces listed above was conducted. Dynamic fatigue testing according to ISO 14801 was conducted to determine the abutments are strong enough for their intended use. The steam sterilization instructions were validated by the biological indicators over kill method. An SAL of $\leq 10^{-6}$ was validated. Dry time was validated using full cycle parameters. Materials used in the product meet ASTM F136 and the biocompatibility was demonstrated by testing the cytotoxicity according to ISO 10993-5.

Predicate Device: Primary Predicate Atlantis Abutments K053654 and Reference Predicates Atlantis Abutments K981858, Replace TiUnite Endosseous Implant K023113, and Replace HA Coated Implant K020646

Substantial Equivalence:
Allied Biocompat abutments are substantially equivalent to Atlantis Abutments in indications for use (except for the slightly less max angulation, early loading, and highly angled abutment statements that do not change the intended use and are addressed in the labeling), materials, design, and fatigue performance. Fatigue testing according to ISO 14801 was completed for Allied Biocompat abutments and was successful. Both Allied Biocompat and Atlantis successfully completed ISO 14801 fatigue tests.

Company	Allied Biocompat Abutments	Atlantis Abutments K053654 and K981858
Indications for Use	The Allied Biocompat abutment is intended for use with 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 prosthesis can be cemented or screw retained to the abutment. The abutment screw is intended to secure the Allied Dental Solutions abutment to the endosseous implant. Allied Biocompat Abutments are compatible with the following Implant Manufacturer: Nobel Biocare Implant Line: Replace Select	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 prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. This device is compatible with Nobel Biocare Replace Select Straight, Replace Select Straight One Stage, Replace Select Tapered and Replace Select

	Straight and Select Straight One Stage, Replace Select Tapered and Select Tapered One Stage Implant Diameters: 3.5 (NP), 4.0 (RP), 5.0 (WP) and 6.0	Tapered One Stage. This device may be used in an early loading situation, but is dependent on the specific implant system and protocol used by the dental professional. Highly angled abutments (i.e.30 degrees) on implants with diameters less than 4mm are intended for the anterior region of the mouth and are not intended for the posterior region due to limited strength of the implant.
Diameters	3.5, 4.3, 5, 6	3.5, 4.3, 5, 6
Material	Ti-6AL-4V ELI	Ti-6AL-4V ELI
Fatigue testing	Passed testing according to ISO 14801	Passed testing according to ISO 14801
Type of abutment and maximum angulation	Patient-specific of no more than 25°	Patient-specific of no more than 30°
Interface type/shape	NB internal tri-lobe	NB internal tri-lobe

The reference predicates K020646 and K023113 demonstrate substantial equivalence for the implants listed as compatible with the Allied Biocompat abutment.

Conclusion:
Allied Biocompat abutments are substantially equivalent to Atlantis Abutments. They both have the same indications for use (with the exceptions mentioned above), are of the same material, fit the same implants (thus have identical interfaces), and both passed ISO 14801 fatigue testing successfully. Allied Biocompat abutments have a smaller maximum angulation because the software controlling the design limits for milling made designs with larger angulation than 25° undesirable due to other parameters like diameter, height, etc. Restricting the angulation does not affect the substantial equivalence.

The Allied Biocompat abutment is intended for use with 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 prosthesis can be cemented or screw retained to the abutment. The abutment screw is intended to secure the Allied Dental Solutions abutment to the endosseous implant.