K101755

NOV 2 2 2010

510 (K) Summary of Safety and Effectiveness (Revised on 10/7/2010)

Submitted by:	William Yuen-Siang hung, D.D.S., J.D.
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Date of Submission:	May 18th, 2010
Classification Name	Endosseous dental implant 21 CFR 872.3640 and endosseous dental implant abutment 21 CFR 872.3630
Trade Name:	AIDI Dental Implant System
Legally Marketed Device	NobelActive™ Internal Connection Implant (K071370) IDI™ Implant System (K081860)

1. Device Description:

AIDI Dental Implant System (AIDI) is a threaded root-form dental implant intended for use (function) in the upper and lower jaw arches to support prosthetic devices, such as an artificial tooth, in order to restore esthetics and chewing function to partially or fully edentulous patients. Also included are straight abutments which provide cemented and screw retained restorative options.

AIDI is an improved version of the predicated IDI Implant System (IDI). AIDI has the same scientific concepts as predicated IDI which include same internal connection design, same internal thread at apical end, same thread design at external surfaces and same surface treatment which is Soluable Blast Media (SBM).

The physical and performance characteristic of AIDI, predicated IDI and predicated NobelActive Dental Implant (NA) includes gradually expanding tapered implant body allowing for alveolar bone expanding and condensing capabilities. The material composition of AIDI and predicated IDI are Titanium ASTM F67 Grade 4 or ASTM F-136 6AL4V ELI. AIDI is also similar to predicated NA Implants in tapered coronal design and hex-cavity internal connection design.

4. Nonclinical Test Summary

The nonclinical test data of AIDI Dental Implant System Torque Test Report revealed a high torque strength for AIDI Dental Implants. The predicated IDI™ implant and predicated NobelActive™ dental implant resembled the same torque strength.

5. Clinical Test Summary

No clinical studies are submitted.

6. Conclusion

In Sum, we can conclude that AIDI Dental Implant System (K101755) is safe and effective for its intended use and performs as well as predicated IDI Implant System (K081806) and predicated NobelActive Internal Connection Implant System (K071370) for the following reasons:

A. The torque strength test data revealed a high torque strength for AIDI Dental Implants. The predicated IDI™ implant system and predicated NobelActive™ Internal Connection Implant System resembled the same torque strength.

B. IDI Implant System (K081806) and NobelActive Internal Connection Implant System (K071370) are substantially equivalent to AIDI dental implant system (K101755) regarding materials, design and technological characteristics.

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

Dr. William Y.S. Hung
Chief Executive Office
AIDI BioMedical, LLC
34859 Frederick Street, #105
Wildomar, California 92595

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Re: K101755
Trade/Device Name: AIDI Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: October 7, 2010
Received: October 14, 2010

Dear Dr. Hung:

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.

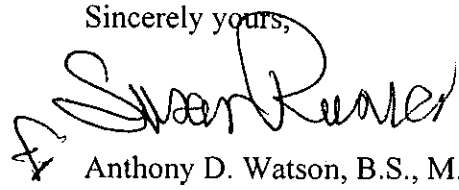
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

Enclosure

K101755

Indications for Use:

AIDI Dental Implant Systems® (AIDI Fixtures and AIDI Abutments with screws) are endosseous implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Straight abutments indicated for both screw retained and cemented restorations are included. The implants are indicated for single or multiple unit restorations and can be used in splinted and non-splinted applications. The device is intended for immediate placement and immediate loading when good primary stability has been achieved and with appropriate occlusal loading.

Prescription Use x (Part 21 CFR801 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)

Susan Runyan

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

510(k) Number: K101755

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2. Indication for Use

AIDI Dental Implant Systems are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetics devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. The device is intended for immediate placement and immediate loading when good primary stability has been achieved and with appropriate occlusal loading.

3. Technological Characteristics

	Subject Device	Predicate Devices	
Name	AIDI Dental Implant System (AIDI Internal Fixture and Abutments) (K101755)	NobelActive Internal Connection Implant System and Abutments (K071370)	IDI Implant Systems (IDI Internal Fitures and Abutments) (K081806)
Material	Titanium ASTM F67 Grade 4 or ASTM F-136 6AL4V ELI	Titanium ASTM F67 Grade 4 or ASTM F-136 6AL4V ELI	Titanium ASTM F67 Grade 4 or ASTM F-136 6AL4V ELI
Coronal Design	Tapered Coronal Design	Back-Tapered Coronal Design	No
Internal Screw Thread	Yes	Yes	Yes
Implant Body Design	Tapered	Tapered	Tapered
Implant Body Diameter (mm)	3.2, 3.7, 4.7, 5.4	3.5, 4.3, 5.0	3.7, 4.7, 5.4, 6.4
Length (mm)	8.8~16.0	8.5~18.0	8.8~16.0
One-Stage Surgical Procedures	Yes	Yes	No
Two-Stages Surgical Procedures	Yes	Yes	Yes
Implant/ Abutment Interface	Hexagonal Interlocking	Hexagonal Interlocking	Hex-Lobe Interlocking
Surface Treatment	Soluable Blast Media (Tricalcium Phosphate/ Hydroxyapatite, conform to ASTM F1185-03)	TiUnite	Resorbable media Blasting (Tricalcium Phosphate/ Hydroxyapatite, conform to ASTM F1185-03)
Gamma Sterilized	Yes	Yes	Yes
Attachments	Screw-retained restoration system	Screw-retained restoration system	Screw-retained restoration system