DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 31, 2015

Digitek Dental Solutions Limited
Mr. Alwin Ngai
Director
Units B-C Flat D, 6/F, Dragon Ind. Bldg.,
93 King Lam St., Cheung Sha Wan,
Kowloon, Hong Kong

Re: K141970
Trade/Device Name: Digitek Titanium Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: June 19, 2015
Received: July 02, 2015

Dear Mr. Ngai,

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 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. 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 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141970

Device Name
Digitek Titanium Abutment

Indications for Use *(Describe)*
Digitek Titanium Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. They are compatible with the ASTRA TECH Implant System OsseoSpeed™ 3.5mm, 4.0mm, 4.5mm, 5.0mm implants

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5: 510(k) Summary

1. Submitter Information

Company Name:	Digitek Dental Solutions Limited
Company Address:	Units B-C, Flat D, 6/F, Dragon Ind. Bldg., 93 King Lam St., Cheung Sha Wan, Kowloon, Hong Kong
Company Phone:	(852) 2742 3210
Company Fax:	(852) 3590 8715
Contact Person:	Alwin Ngai
Date Prepared	July 29, 2015

2. Device Identification

Device Model Name:	Digitek Titanium Abutment
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	872.3630
Product Code:	NHA
Class	II
Panel	Dental

3. Predicated Devices

Primary Predicate Device	Inclusive® Titanium Abutment for - Astra OsseoSpeed™ Implants, K100993
Reference predicate Device	GC AADVA TI ABUTMENTS – BO AC SV BH, K103234

4. Device Description

Digitek Titanium Abutments are endosseous implant abutments which are placed into a corresponding dental implant to provide support for a prosthetic restoration. These abutments are made of titanium grade Ti-6Al-4V ELI (meets ASTM Standard F136). The abutment is mounted into the implant with a screw. These abutments are compatible with the ASTRA TECH Implant System OsseoSpeed™ implants.

Digitek Titanium Abutments are provided straight only and are not intended to be modified to provide an angle correction.

Digitek Titanium Abutments are manufactured in two models “3.5” and “4.0”. And a hexagonal prism at the base of the Digitek Titanium Abutments acts as an anti-rotation feature.

Digitek titanium Abutments are supplied in a non-sterile state and should be sterilized prior to installation.

5. Indication for Use

Digitek Titanium Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. They are compatible with the ASTRA TECH Implant System OsseoSpeed™ 3.5mm, 4.0mm, 4.5mm, 5.0mm implants.

6. Substantial Equivalence

The proposed Digitek Titanium Abutments are substantially equivalent to the Inclusive® Titanium Abutments for - Astra OsseoSpeed™ Implants, and the GC AADVA TI ABUTMENTS - BO AC SV BH. These abutments are substantially equivalent in indications for use, material of body and screw, design and sterility status.

Elements of Comparison	Subject Device	Primary Predicate Device	Reference Predicate Device
Name	Digitek Titanium Abutments	Inclusive® Titanium Abutments for - Astra OsseoSpeed™ Implants	GC AADVA TI ABUTMENTS - BO AC SV BH
510(k) Number	Applying	K100993	K103234
Indications for Use	Digitek Titanium Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. They are compatible with the ASTRA TECH Implant System	Inclusive® Titanium Abutments for - Astra OsseoSpeed™ Implants are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. They are compatible with the Astra Tech	"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

	OsseoSpeed™ 3.5mm, 4.0mm, 4.5mm, 5.0mm implants.	OsseoSpeed™ 3.0, 3.5, 4.0, 4.5, 5.0 implants.	screw in order to engage corresponding dental implant fixture.
Material of Body and Screw	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V
Design	Abutment (main body) assembly with abutment screw. Abutment connection to implant is an internal hexagon	Implant/Abutment assembly with abutment screw. Abutment connection to implant is an internal hexagon	Allows the prosthesis to be retained to the abutment; abutment screw is intended to secure the abutment to the endosseous dental implant
Abutment Platform Diameters (mm)	3.5, 4.0, 4.5, 5.0mm	3.0, 3.5, 4.0, 4.5, 5.0mm	Max. 6.0mm Min. 2.5mm
Sterility Status	Supplied in non-sterile state	Supplied in non-sterile state	Supplied in non-sterile state

7. Performance Testing

Fatigue testing was performed according to ISO 14801:2007, Dentistry -- Implants -- Dynamic fatigue test for endosseous dental implants. Testing was performed on Digitek Titanium Abutment with the implants that they are intended to fit.

Final finished sterilized Digitek Titanium Abutment has been tested for cytotoxicity according to ISO 10993-5.

Sterilization method has been validated according to ANSI/AAMI ST79.

Reverse engineering analysis was performed on OEM abutments to obtain data used in the design the Digitek Titanium Abutment.

The Digitek Titanium Abutment conforms to the FDA Guidance Document for Endosseous Dental Implants and Abutments.

8. Conclusion

There are no known technological differences between Digitek Titanium

Abutments and those of the predicate devices. Thus, Digitek Titanium Abutments is substantially equivalent to the predicate devices.