ids - integrated dental systems
% Kevin Thomas
Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

March 29, 2019

Re: K180924
Trade/Device Name: Reflect™ Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: February 27, 2019
Received: February 28, 2019

Dear Kevin Thomas:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S3

Digitally signed by Mary S. Runner -S3
Date: 2019.03.29 08:25:58 -04'00'

For Tina Kiang, Ph.D.
Acting 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)*

K180924

Device Name

Reflect™ Implant System

Indications for Use (Describe)

Reflect™ Dental Implants are indicated for use in partially or fully edentulous patients to support maxillary and mandibular single-unit, multiple-unit, and overdenture dental restorations. Reflect™ Dental Implants are indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.
Reflect™ Implant System prosthetic components are compatible with the following implant systems.

Implant System Compatibility	Implant Body Diameter (mm)	Platform Diameter (mm)
OsseoSpeed™	3.5	3.5/4.0
	4.0	3.5/4.0
	5.0	4.5/5.0
3i Certain®	3.25	3.4
	4.0	4.1
	5.0	5.0
NobelActive®	3.5	NP
	4.3	RP
	5.0	RP
NobelReplace Conical	3.5	NP
	4.3	RP
	5.0	RP
Tapered Screw-Vent®	3.7	3.5
	4.1	3.5
	4.7	4.5

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

ids – integrated dental solutions

Reflect™ Implant System

March 28, 2019

ADMINISTRATIVE INFORMATION

Manufacturer Name	ids – integrated dental systems 300 Sylvan Avenue, Suite 104 Englewood Cliffs, NJ 07632 Telephone: +1 201-676-2456 Fax: +1 888-788-3297
Official Contact	Matthew Grella, Quality Assurance & Regulatory Affairs Director
Representative/Consultant	Kevin A. Thomas, PhD Floyd G. Larson, MS, MBA PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 858-792-1235 Fax: +1 858-792-1236 Email: kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Reflect™ Implant System
Common Name	Endosseous dental implant Endosseous dental implant abutment
Classification Regulations	21 CFR 872.3640
Primary Product Code	DZE
Secondary Product Code	NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary predicate device:
K120414, OsseoSpeed™ Plus, Astra Tech AB

Reference devices: *Compatible Systems*
K101732, Astra Tech Implant System, Astra Tech AB
K063341, 3i OSSEOTITE® Certain® Dental Implants, Implant Innovations, Inc.
K142260, NobelActive®, Nobel Biocare AB
K073142, NobelReplace Hexagonal Implant, Nobel Biocare AB
K111889, Tapered Screw-Vent® M, Zimmer Dental, Inc.

INDICATIONS FOR USE STATEMENT

Reflect™ Dental Implants are indicated for use in partially or fully edentulous patients to support maxillary and mandibular single-unit, multiple-unit, and overdenture dental restorations. Reflect™ Dental Implants are indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.
Reflect™ Implant System prosthetic components are compatible with the following implant systems.

Implant System Compatibility	Implant Body Diameter (mm)	Platform Diameter (mm)
OsseoSpeed™	3.5	3.5/4.0
	4.0	3.5/4.0
	5.0	4.5/5.0
3i Certain®	3.25	3.4
	4.0	4.1
	5.0	5.0
NobelActive®	3.5	NP
	4.3	RP
	5.0	RP
NobelReplace Conical	3.5	NP
	4.3	RP
	5.0	RP
Tapered Screw-Vent®	3.7	3.5
	4.1	3.5
	4.7	4.5

DEVICE DESCRIPTION

Reflect™ Implant System implants are root form endosseous dental implants with a tapered body and a grit blasted and acid etched surface intended for bone level placement. The subject device consists of five product lines (Reflect™ Aspire, Reflect™ Certus, Reflect™ Rapid, Reflect™ Recover, and Reflect™ Tapered) and three component designs (Cover Screw, Healing Abutment, and 30° Abutment). The Reflect™ implant sizes are summarized in the following table.

Reflect™ Implant System			
Implant Line	**Body Ø (mm)**	**Platform Ø (mm)**	**Implant Lengths (mm)**
Aspire	3.5	3.5	8, 9, 11, 13, 15
	4.0	4.0	8, 9, 11, 13, 15
	5.0	5.0	9, 11, 13, 15
Certus	3.3	3.4	8.5, 10, 11.5, 13, 15
	4.0	4.1	8.5, 10, 11.5, 13, 15
	4.9	5.0	8.5, 10, 11.5, 13, 15
Rapid	3.5	NP	8.5, 10, 11.5, 13, 15
	4.3	RP	8.5, 10, 11.5, 13, 15
	5.0	RP	8.5, 10, 11.5, 13, 15
Recover	3.5	NP	8.5, 10, 11.5, 13, 16
	4.3	RP	8.5, 10, 11.5, 13, 16
	5.0	RP	8.5, 10, 11.5, 13, 16
Tapered	3.7	3.5	8.5, 10, 11.5, 13, 16
	4.1	3.5	8.5, 10, 11.5, 13, 16
	4.7	4.5	8.5, 10, 11.5, 13, 16

The Reflect™ abutment sizes are summarized in the following table. Note: each abutment is provided in each platform diameter listed.

Reflect™ Implant System – Abutments			Compatible Implants	
Implant Line	**Abutments**	**Abutment Platform Ø (mm)**	**Implant System Compatibility**	**Platform Diameters (mm)**
Aspire	Aspire Cover Screw	3.5, 4.0, 5.0	OsseoSpeed™	3.5/4.0, 4.5/5.0
	Aspire Ø 3.5/4.0 mm Healing Abutment	3.5, 4.0	OsseoSpeed™	3.5/4.0
	Aspire Ø 4.5/5.0 mm Healing Abutment	5.0	OsseoSpeed™	4.5/5.0
	Aspire 30° Abutment	3.5, 4.0, 5.0	OsseoSpeed™	3.5/4.0, 4.5/5.0
Certus	Certus Cover Screw 3.4/4.1 mm	3.4, 4.1	3i Certain®	3.4, 4.1
	Certus Cover Screw 5.0 mm	5.0	3i Certain®	5.0
	Certus Healing Abutment	3.4, 4.1, 5.0	3i Certain®	3.4, 4.1, 5.0
	Certus 30° Abutment	3.4, 4.1, 5.0	3i Certain®	3.4, 4.1, 5.0
Rapid	Rapid Cover Screw	NP, RP	NobelActive®	NP, RP
	Recover/Rapid Healing Abutment	NP, RP	NobelActive®	NP, RP
	Rapid 30° Abutment	NP, RP	NobelActive®	NP, RP
Recover	Recover Cover Screw	NP, RP	NobelReplace Conical	NP, RP
	Recover/Rapid Healing Abutment	NP, RP	NobelReplace Conical	NP, RP
	Recover 30° Abutment	NP, RP	NobelReplace Conical	NP, RP
Tapered	Tapered Cover Screw	3.5, 4.5	Tapered Screw-Vent®	3.5, 4.5
	Tapered Healing Abutment	3.5, 4.5	Tapered Screw-Vent®	3.5, 4.5
	Tapered 30° Abutment	3.5, 4.5	Tapered Screw-Vent®	3.5, 4.5

Subject device implants are made of unalloyed titanium conforming to ASTM F67 *Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)* Grade 4, and subject device abutments are made of titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).*

The subject device implant surface is produced by blasting with alumina (Al_2O_3) powder, and etching with hydrochloric acid and sulfuric acid. After etching, the remaining acid is removed by washing with distilled water, followed by cleaning with an alkaline solution using a high temperature and high-pressure hydrothermal method.

PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include: sterilization validation according to ISO 11137-1, ISO 11137-2, ISO 17665-1, and 17665-2; biocompatibility according to ISO 10993-1, 10993-5, and 10993-12; dynamic compression-bending testing according to ISO 14801; and engineering and dimensional analysis of the OEM implant bodies, OEM abutments, and OEM fixation screws. No clinical data were included in this submission.

For components provided sterile (implants, cover screws, and healing abutments) bacterial endotoxin testing was performed according to ANSI/AAMI ST72. Sterile barrier shelf testing was performed according to ASTM standards F88, F1140, F2096, F1929, and F1608.

Scanning electron microscopy (SEM) with energy dispersive X-ray spectroscopy (EDS) was performed on the implant endosseous threaded surface to confirm there was no residual material from the blasting or cleaning operations present on the final devices.

EQUIVALENCE TO MARKETED DEVICE

Provided at the end of this summary is a table comparing the Indications for Use Statements and the technological characteristics of the subject device and the primary predicate device K120414.

The subject device is substantially equivalent to the primary predicate, K120414, in material, implant design and surface, abutment design, clinical operating principle and intended use. The subject device implants and abutments are provided in the same range of sizes and dimensions as the primary predicate as shown in the table above.

Slight differences in the language between the subject device and predicate device Indications for Use Statements do not affect the intended use as a support for single or multi-unit restorations in the maxilla or mandible for the restoration of chewing function, with immediate loading indicated when primary stability and appropriate occlusal loading are achieved. The difference is that the primary predicate has additional phrases based on specific claims or specific restrictions placed on individual devices. Also, additional language for the primary predicate is related to device types/dimensions/designs that are not included in the subject device system.

Implant connection and body design are substantially equivalent to the compatible system reference devices K101732, K063341, K142260, K073142, K111889. Engineering and dimensional analysis were conducted to confirm compatibility.

The subject device components are made of similar materials, have similar packaging and are sterilized using similar materials and processes as the primary predicate device.

CONCLUSION

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject device and predicate devices encompass the same range of physical dimensions, including diameter and length of the implants, and the diameter and angulation of the abutments. The subject and predicate devices are packaged in similar materials and sterilized using similar methods.

The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

Comparison of Indications for Use Statements and Technological Characteristics

<table>
<tr><th></th><th>Subject Device</th><th>Primary Predicate Device</th></tr>
<tr><td>Comparison</td><td>K180924
Reflect™ Implant System
ids – integrated dental systems</td><td>K120414
OsseoSpeed™ Plus
Astra Tech AB</td></tr>
<tr><td>Indications for Use Statement</td><td>Reflect™ Dental Implants are indicated for use in partially or fully edentulous patients to support maxillary and mandibular single-unit, multiple-unit, and overdenture dental restorations. Reflect™ Dental Implants are indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.
Reflect™ Implant System prosthetic components are compatible with the following implant systems.

<table><tr><th>Implant System Compatibility</th><th>Implant Body Diameter (mm)</th><th>Platform Diameter (mm)</th></tr><tr><td>OsseoSpeed™</td><td>3.5</td><td>3.5/4.0</td></tr><tr><td></td><td>4.0</td><td>3.5/4.0</td></tr><tr><td></td><td>5.0</td><td>4.5/5.0</td></tr><tr><td>3i Certain®</td><td>3.25</td><td>3.4</td></tr><tr><td></td><td>4.0</td><td>4.1</td></tr><tr><td></td><td>5.0</td><td>5.0</td></tr><tr><td>NobelActive®</td><td>3.5</td><td>NP</td></tr><tr><td></td><td>4.3</td><td>RP</td></tr><tr><td></td><td>5.0</td><td>RP</td></tr><tr><td>NobelReplace Conical</td><td>3.5</td><td>NP</td></tr><tr><td></td><td>4.3</td><td>RP</td></tr><tr><td></td><td>5.0</td><td>RP</td></tr><tr><td>Tapered Screw-Vent®</td><td>3.7</td><td>3.5</td></tr><tr><td></td><td>4.1</td><td>3.5</td></tr><tr><td></td><td>4.7</td><td>4.5</td></tr></table></td><td>Implants:
OsseoSpeed™ Plus
The Astra Tech Dental Implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols:
• replacing single and multiple missing teeth in the mandible and maxilla,
• immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge,
• especially indicated for use in soft bone applications where implants with other implant surface treatments may be less effective,
• immediate loading in all indications, except in single tooth situations on implants shorter than 8 mm or in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate.
The intended use for OsseoSpeed™ Plus 3.0S is limited to replacement of maxillary lateral incisors and mandibular incisors.
Abutments:
Astra Tech Implant System Plus abutments are intended to be used· in conjunction with Astra Tech Implant System Plus in fully edentulous or partially edentulous maxillary and/or mandibular arches to provide support for crowns, bridges or overdentures.
Atlantis™ Abutments:
The Atlantis 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, screw retained or friction fit to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.
The Atlantis™ Crown Abutment in Zirconia is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in partially or completely edentulous patients. The prosthesis is screw retained. The abutment screw is intended to secure the crown abutment to the endosseous implant.</td></tr>
<tr><td>Design</td><td></td><td></td></tr>
<tr><td>Implant Body Diameter (mm)</td><td>3.3, 3.5, 3.7, 4.0, 4.1, 4.3, 4.7, 4.9, 5.0</td><td>3.0, 3.6, 4.2, 4.8, 5.4</td></tr>
<tr><td>Implant Length (mm)</td><td>8.0, 8.5, 9.0, 10, 11, 11.5, 13, 15, 16</td><td>6.0, 8.0, 9.0, 11, 13, 15, 17</td></tr>
<tr><td>Implant Platform Diameter (mm)</td><td>3.4, 3.5, 4.0, 4.1, 4.5, 5.0, NP, RP</td><td>3.0, 3.6, 4.2, 4.8, 5.4</td></tr>
<tr><td>Abutment Platform Diameter (mm)</td><td>3.4, 3.5, 4.0, 4.1, 4.5, 5.0, NP, RP</td><td>3.0, 3.6, 4.2, 4.8, 5.4</td></tr>
<tr><td>Abutment Angle</td><td>Up to 30°</td><td>Up to 30°</td></tr>
<tr><td>Abutment/ Implant Interface</td><td>Internal Hex</td><td>Internal Hex</td></tr>
<tr><td>Materials</td><td></td><td></td></tr>
<tr><td>Implant</td><td>Unalloyed Titanium Gr 4</td><td>Unalloyed Titanium Gr 4</td></tr>
<tr><td>Implant Endosseous Surface</td><td>Grit-blasted and acid-etched</td><td>OsseoSpeed</td></tr>
<tr><td>Abutment</td><td>Titanium Alloy</td><td>Titanium Alloy</td></tr>
<tr><td>Screw</td><td>Titanium Alloy</td><td>Titanium Alloy</td></tr>
</table>