April 27, 2021

Integrated Dental Systems LLC
% Kevin Thomas
Vice President and Director of Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K203240
Trade/Device Name: AccelX™ Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: March 29, 2021
Received: March 29, 2021

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203240

Device Name

AccelX™ Abutments

Indications for Use *(Describe)*

AccelX™ Abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for single-unit or multi-unit prosthetic restorations.

All digitally designed abutments for use with AccelX™ CAD-CAM Abutments are intended to be sent to an Integrated Dental Systems validated milling center for manufacture.

AccelX™ Abutments are compatible with MegaGen AnyRidge Internal Implant System components as listed below.

Implant System Compatibility	Implant Body Diameter, mm	Implant Platform, mm
MegaGen AnyRidge Internal Implant System	4.0	3.5
	4.4	3.5
	4.9	3.5
	5.4	3.5
	5.9	3.5
	6.4	5.0
	6.9	5.0
	7.4	5.0
	7.9	5.0
	8.4	5.0

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
K203240
AccelX™ Abutments
Integrated Dental Systems, LLC

April 27, 2021

ADMINISTRATIVE INFORMATION

Manufacturer Name	Integrated Dental Systems, LLC 145 Cedar Lane Englewood, New Jersey 07631 Telephone +1 917-693-5595
Official Contact	David Singh, Chief Operating Officer
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	AccelX™ Abutments
Common Name	Dental implant abutment
Regulation Number	21 CFR 872.3630
Regulation Name	Endosseous dental implant abutment
Regulatory Class	Class II
Product Code	NHA
Classification Panel	Dental
Reviewing Office	Office of Health Technology 1 (Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices)
Reviewing Division	Division of Health Technology 1 B (Dental Devices)

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K191986, DESS Dental Smart Solutions, Terrats Medical SL

Additional Predicate Devices
K123988, AnyOne™ Internal Implant System, MegaGen Implant Company, Limited
K182448, AnyRidge Octa 1 Implant System, MegaGen Implant Co., Ltd.
K140091, Xpeed AnyRidge Internal Implant System, MegaGen Implant Co., Ltd.
K140728, Dental Implants and Abutments, Ditron Precision Ltd.

K191986 is the primary predicate for support of substantial equivalence in terms of Indications for Use, CAD-CAM abutments, and referenced sterilization and biocompatibility data. The additional predicates K123988 and K182448 are for support of substantial equivalence in terms of component designs. The predicate K140091 is for support of substantial equivalence in terms of the OEM compatibilities. The additional predicate K140728 is for referenced sterilization and biocompatibility data.

INDICATIONS FOR USE STATEMENT

AccelX™ Abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for single-unit or multi-unit prosthetic restorations.

All digitally designed abutments for use with AccelX™ CAD-CAM Abutments are intended to be sent to an Integrated Dental Systems validated milling center for manufacture.

AccelX™ Abutments are compatible with MegaGen AnyRidge Internal Implant System components as listed below.

Implant System Compatibility	Implant Body Diameter, mm	Implant Platform, mm
MegaGen AnyRidge Internal Implant System	4.0	3.5
	4.4	3.5
	4.9	3.5
	5.4	3.5
	5.9	3.5
	6.4	5.0
	6.9	5.0
	7.4	5.0
	7.9	5.0
	8.4	5.0

SUBJECT DEVICE DESCRIPTION

AccelX™ Abutments comprises conventional and CAD-CAM abutments, abutment screws, and other associated components compatible with MegaGen AnyRidge Internal Implant System.

AccelX™ conventional abutments and prosthetic components include Cover Screws, Healing Abutments, Temporary Abutments, Prepable Straight Abutments, Angled Abutments, Castable Base Abutments, and Multi-Unit Abutments. All conventional abutments and prosthetic components are manufactured from Ti-Al-4V alloy conforming to ASTM F136 except the Castable Base Abutments that are manufactured from Co-Cr-Mo alloy conforming to ASTM F1537.

AccelX™ CAD-CAM abutments include Titanium Base Abutments for use with a zirconia coping, and Titanium Blank Abutments to be milled to a final one-piece abutment. Titanium Base Abutments are two-piece abutments composed of the titanium base component and a zirconia top-half, which comprises the final abutment once the two components are cemented together using CemPlant Implant Cement. The Titanium Base Abutments and Titanium Blank Abutments are manufactured from Ti-Al-4V alloy conforming to ASTM F136. The zirconia copings for the Titanium Base Abutments will be manufactured

from zirconia conforming to ISO 13356. All digitally designed abutments for use with AccelX™ CAD-CAM abutments are intended to be sent to an Integrated Dental Systems validated milling center for manufacture. The AccelX™ abutments and prosthetic components are summarized in the following table.

AccelX™ Abutments and Abutment Screws

	Coronal Ø, mm	**Angle**	**Material**
Cover Screws	3.5	n/a	Titanium alloy, ASTM F136
Healing Abutments	4, 5, 6, 7, 8, 10	n/a	Titanium alloy, ASTM F136
	Prosthetic Platform Ø, mm		
Temporary Abutments	4	n/a	Titanium alloy, ASTM F136
Prepable Straight Abutments	4, 5, 6, 7; 4.5, 5.5, 6.5	n/a	Titanium alloy, ASTM F136
Angled Abutments	4, 5, 6, 7	15°, 25°	Titanium alloy, ASTM F136
Castable Base Abutment - Co-Cr-Mo Alloy	3.8	0°	Co-Cr-Mo alloy, ASTM F1537
Multi-Unit Abutments	4.8	0°, 17°, 30°	Titanium alloy, ASTM F136
Titanium Base Abutments	4.0, 4.4	0° (coping)	Titanium alloy, ASTM F136 Zirconia, ISO 13356
Titanium Blank Abutments	6.9 (or per available space)	Up to 30°	Titanium alloy, ASTM F136
Abutment Multi Post Screw **Multi-Unit Abutment Screw** **Multi-Unit Prosthetic Screw**	n/a	n/a	Titanium alloy, ASTM F136

The subject device abutments and healing components are compatible with MegaGen AnyRidge Internal System components (K140091).

PERFORMANCE DATA

The subject device was evaluated and tested as recommended in the FDA guidance documents *Root Form Endosseous Dental Implants and Endosseous Dental Implant Abutments* (issued May 12, 2004), and *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* (issued September 4, 2020).

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include: moist heat (steam) sterilization according to ISO 17665-1, and ISO 17665-2 (included in this submission and referenced from K140728 and K191986); biocompatibility data for the ASTM F136 titanium alloy (included in this submission and referenced from K191986), for the ASTM F1537 Co-Cr-Mo alloy (referenced from K191986), and included in this submission for the ISO 13356 zirconia material used to fabricate copings for Titanium Base Abutments. Testing to demonstrate compatibility to the OEM system included reverse engineering of OEM implant bodies, OEM abutments, and OEM abutment screws, and static compression and compression fatigue testing according to ISO 14801.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

The subject devices are substantially equivalent in indications and design principles to the primary predicate device and the additional predicate devices listed above. Provided at the end of this summary is a table comparing the Indications for Use Statements and a table comparing the technological characteristics of the subject device, the primary predicate device, and the additional predicate devices.

The Indications for Use Statement (IFUS) for the subject device is substantially equivalent to that of the primary predicate K191986 and to the additional predicate devices. Slight differences in the language of the IFUS do not affect the intended use as dental implant abutments for support of a prosthesis to restore chewing function.

Minor differences between the IFUS for the subject device and the primary predicate device K191986 include differences in tradenames, differences in validated milling centers, differences in the compatible OEM implant systems, and K191986 is limited to abutments for CAD-CAM technology. These minor differences do not raise new questions of safety or effectiveness because both IFUS express equivalent intended use.

Minor differences between the IFUS for the subject device and the additional predicate devices K123988, K182448, and K140091 include: the subject device IFUS includes the term "single-unit or multi-unit prosthetic restorations" and the predicate devices use alternative terminology "Crown, bridges, and overdentures"; the subject device IFUS includes references to CAD-CAM technology to fabricate patient-specific abutments, validated milling centers, and compatible OEM implant systems and the additional predicate IFUS does not include these elements; and differences in tradenames. These minor differences do not raise new questions of safety or effectiveness because all IFUS express equivalent intended use.

Subject Device Abutments

The following subject device designs are substantially equivalent to the predicate device K123988: Cover Screws, Healing Abutments, Temporary Abutments, Prepable Straight Abutments, and Angled Abutments. These subject device prosthetic components and the corresponding predicate device prosthetic components are all manufactured from titanium alloy and are compatible with the MegaGen AnyRidge Internal Implant System. The subject device Cover Screws have a coronal diameter 3.5 mm, and provided in cuff heights ranging from 1 mm to 2.8 mm. The predicate device cover screws have a coronal diameter 3.5 mm, and provided in cuff heights ranging from 0.8 mm to 2.6 mm. Both the subject device and predicate device are threaded to match the internal thread of the implant. The subject device Healing Abutments and the predicate device healing abutments have a coronal diameter ranging from 4 mm to 10 mm, cuff heights ranging from 3 mm to 7 mm, and are threaded to match the internal thread of the implant. The subject device Temporary Abutments and the predicate device temporary abutments have a 2 mm cuff height, a 4 mm prosthetic platform diameter, and a 10 mm prosthetic post. The subject device Prepable Straight Abutments and the predicate device EZ Post Abutments have a cuff height ranging from 2 mm to 5 mm, prosthetic platform diameters ranging from 4 mm to 7 mm, and a prosthetic post of 5.5 mm or 7 mm. The subject device Angled Abutments and predicate device angled abutments have a cuff height ranging from 2 mm to 5 mm, prosthetic platform diameters ranging from 4 mm to 7 mm, a prosthetic post of 7 mm, and an angle of 15° or 25°.

The subject device Multi-Unit Abutments designs are substantially equivalent to the predicate device K182248. The subject device and predicate device abutments are for multi-unit restorations, have a

prosthetic diameter of 4.8 mm, include angulations of 0°, 17°, and 30°, have an internal implant interface connection, and are manufactured from titanium alloy. The subject device and predicate device abutments with angulation of 0° are provided in cuff heights ranging from 1.3 mm to 4.3 mm. The subject device abutments with angulation of 17° are provided with cuff heights ranging from 2.5 mm to 4.5 mm. The subject device abutments with angulation of 30° are provided with cuff heights 3.5 mm and 4.5 mm. The predicate device abutments with angulation of 17° and 30° are provided with cuff heights ranging from 2.3 mm to 4.3 mm. The subject device Multi Unit Abutment Cylinder (coping) is substantially equivalent in material and design to the predicate device cylinder (coping) cleared in K182248.

The subject device Castable Base Abutment – Co Cr Mo Alloy design is substantially equivalent to the predicate device K182248. The subject and predicate device abutments are bases for a final abutment fabricated by the traditional cast-to (lost wax) method with non-precious alloys, without angulation. The subject and predicate devices have a prosthetic diameter of 3.8 mm.

The subject device Titanium Base Abutments designs are substantially equivalent to the predicate K123988. The subject device Titanium Base Abutments have a prosthetic post height of 4.5 mm or 6 mm, with a cut out section in one side of the post to allow for an angled access to the screw channel, and have a cuff height of 0.6 mm or 1.5 mm. The predicate device titanium base abutments have a prosthetic post height of 4.5 mm, 6.0 mm, and 8.0 mm, with a cut out section in one side of the post to allow for an angled access to the screw channel, and have a cuff height of 0.6 mm, 1.5 mm, 3.0 mm, or 4.0 mm. Both the subject device and predicate device titanium base abutments are two-piece abutments composed of a titanium base component and a zirconia top-half, which comprises the final abutment once the two components are cemented together.

The subject device Titanium Blank Abutments are substantially equivalent to the predicate K191986. The overall (milling) diameter of the subject device is 10 mm or 12 mm, and the overall (milling) diameter of the predicate device is 10 mm and 14 mm. Both the subject device and predicate device are manufactured from titanium alloy and are compatible with MegaGen AnyRidge Internal Implant System.

All subject device prosthetic components are provided non-sterile and are to be sterilized to a sterility assurance level (SAL) of 10^{-6} by the end user using the same sterilization method (moist heat) and parameters for devices previously cleared. Sterilization validations for the subject devices were performed according to ISO 17665-1 and ISO TR 17665-2.

The subject device Cover Screws, Healing Abutments, Angled Abutments, Multi Unit Abutments, and Titanium Base Abutments are contract manufactured by Ditron Dental Ltd. for Integrated Dental Systems. The sterilization method and parameters for these subject devices are the same as the predicate device K140728. Therefore, no new sterilization validation was performed because the subject device components are substantially equivalent to the predicate device K140728.

The subject device Temporary Abutments are contract manufactured by Terrats Medical SL for Integrated Dental Systems. The sterilization method and parameters for the subject device Temporary Abutments are the same as the predicate device K191986. Therefore, no new sterilization validation was performed because the subject device components are substantially equivalent to the predicate device K191986.

The subject device Prepable Abutments are contract manufactured by La Precision for Integrated Dental Systems. Sterilization method and parameters were validated according to ISO 17665-1 and ISO TR 17665-2. Similarly, the sterilization method and parameters for subject device Castable Base Abutment –

Co-Cr-Mo Alloy and Titanium Blank Abutments with zirconia superstructure were validated according to ISO 17665-1 and ISO TR 17665-2.

The subject device prosthetic components were evaluated for biocompatibility or tested according to ANSI/AAMI/ISO 10993-5 and ANSI/AAMI/ISO 10993-12.

The subject device Cover Screws, Healing Abutments, Angled Abutments, Multi Unit Abutments, Multi-Unit Abutment Cylinder, and Titanium Base Abutments are contract manufactured by Ditron Dental Ltd. for Integrated Dental Systems. These subject devices are manufactured from titanium alloy, conforming to ASTM F136, in the same facilities using the same manufacturing processes and same materials as used for Ditron Precision components previously cleared in K140728. Confirmatory biocompatibility testing of the titanium alloy was performed according to ISO 10993-5 and ISO 10993-12.

The subject device Temporary Abutments, Titanium Blank abutments, and Castable Base Abutment – Co-Cr-Mo Alloy are contract manufactured by Terrats Medical SL for Integrated Dental Systems. Temporary Abutments and Titanium Blank Abutments are manufactured from titanium alloy conforming to ASTM F136. The Castable Base Abutment – Co-Cr-Mo Alloy are manufactured from cobalt chromium alloy conforming to ASTM F1537. These subject devices are manufactured from the same materials, in the same facilities using the same manufacturing processes as used for Terrats Medical component previously cleared in K191986. Therefore, no new biocompatibility testing was performed, as the subject device Temporary Abutments, Titanium Blank abutments, and Castable Base Abutment – Co-Cr-Mo Alloy are substantially equivalent to the predicate device K191986 with regards to materials and processing.

The subject device Prepable Abutments are contract manufactured by La Precision for Integrated Dental Systems. Prepable Abutments are manufactured from titanium alloy conforming to ASTM F136. Confirmatory biocompatibility testing was tested according to ANSI/AAMI/ISO 10993-5 and ANSI/AAMI/ISO 10993-12 because these subject devices are not manufactured from the same materials, in the same facilities using the same manufacturing processes as a predicate device.

Additional cytotoxicity testing was conducted on the subject device Titanium Base Abutments with zirconia superstructure.

Mechanical performance testing of the subject device was performed in conformance to ISO 14801. The fatigue limit data demonstrated that constructs of the subject device abutments, including abutments fabricated to the limits stated in the proposed labeling, in combination with previously-cleared MegaGen AnyRidge Internal Implant System implants have sufficient strength for their intended use.

Minor differences in the designs, dimensions, sizes, or compatible OEM implant lines among the subject device, the primary predicate device, and the additional predicate devices do not affect substantial equivalence. These minor differences do not impact substantial equivalence because these differences are related to the compatible OEM implant designs or are mitigated by the mechanical performance testing.

CONCLUSION

The subject device, the primary predicate device, the additional predicate devices, and the reference device have the same intended use, have similar technological characteristics, and are made of identical or similar materials. The subject device, the primary predicate, the additional predicate devices, and the

reference device encompass the same range of physical dimensions, are packaged in similar materials, and are sterilized using similar methods.

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

Table of Substantial Equivalence– Indications for Use Statements

<table>
<tr><th></th><th>Indications for Use Statement</th></tr>
<tr><td>Subject Device</td><td></td></tr>
<tr><td>K203240
AccelX™ Abutments
Integrated Dental Systems LLC</td><td>AccelX™ Abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for single-unit or multi-unit prosthetic restorations.
All digitally designed abutments for use with AccelX™ CAD-CAM Abutments are intended to be sent to an Integrated Dental Systems validated milling center for manufacture.
AccelX™ Abutments are compatible with MegaGen AnyRidge Internal Implant System components as listed below.
<table>
<tr><th>Implant System Compatibility</th><th>Implant Body Diameter, mm</th><th>Implant Platform, mm</th></tr>
<tr><td rowspan="10">MegaGen AnyRidge Internal Implant System</td><td>4.0</td><td>3.5</td></tr>
<tr><td>4.4</td><td>3.5</td></tr>
<tr><td>4.9</td><td>3.5</td></tr>
<tr><td>5.4</td><td>3.5</td></tr>
<tr><td>5.9</td><td>3.5</td></tr>
<tr><td>6.4</td><td>5.0</td></tr>
<tr><td>6.9</td><td>5.0</td></tr>
<tr><td>7.4</td><td>5.0</td></tr>
<tr><td>7.9</td><td>5.0</td></tr>
<tr><td>8.4</td><td>5.0</td></tr>
</table></td></tr>
<tr><td>Primary Predicate Device</td><td></td></tr>
<tr><td>K191986
DESS Dental Smart Solutions
Terrats Medical SL</td><td>DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.
All digitally designed custom abutments for use with Ti Base abutments or Pre-milled (Blank) abutments are to be sent to a Terrats Medical validated milling center for manufacture.
Compatible Implant Systems
<table>
<tr><th>Compatible Implant System</th><th>Implant Body Diameter, mm</th><th>Implant Platform</th></tr>
<tr><td>Ankylos C/X</td><td>3.5, 4.5, 5.5</td><td>2.52 mm</td></tr>
<tr><td rowspan="3">Astra Tech EV</td><td>3.6</td><td>2.9 mm</td></tr>
<tr><td>4.2</td><td>3.5 mm</td></tr>
<tr><td>4.8</td><td>4.1 mm</td></tr>
<tr><td rowspan="3">Astra Tech OsseoSpeed™</td><td>3.0</td><td>3.0 mm</td></tr>
<tr><td>3.5/4.0</td><td>3.5/4.0 mm</td></tr>
<tr><td>4.5/5.0</td><td>4.5/5.0 mm</td></tr>
<tr><td rowspan="3">Biomet 3i Certain®</td><td>3.25</td><td>3.45 mm</td></tr>
<tr><td>4.0</td><td>4.1 mm</td></tr>
<tr><td>5.0</td><td>5.0 mm</td></tr>
<tr><td rowspan="3">Biomet 3i OSSEOTITE®</td><td>3.25</td><td>3.4 mm</td></tr>
<tr><td>3.75, 4.0</td><td>4.1 mm</td></tr>
<tr><td>5.0</td><td>5.0 mm</td></tr>
<tr><td rowspan="4">Camlog</td><td>3.3</td><td>3.3 mm</td></tr>
<tr><td>3.8</td><td>3.8 mm</td></tr>
<tr><td>4.3</td><td>4.3 mm</td></tr>
<tr><td>5.0</td><td>5.0 mm</td></tr>
<tr><td rowspan="4">FRIADENT XiVE®</td><td>3.4</td><td>3.4 mm</td></tr>
<tr><td>3.8</td><td>3.8 mm</td></tr>
<tr><td>4.5</td><td>4.5 mm</td></tr>
<tr><td>5.5</td><td>5.5 mm</td></tr>
<tr><td>MegaGen AnyRidge</td><td>3.5, 4.0, 4.5, 5.0, 5.5</td><td>3.5 mm</td></tr>
<tr><td rowspan="4">NobelActive®,
NobelParallel Conical</td><td>3.0</td><td>3.0 (3.0 mm)</td></tr>
<tr><td>3.5</td><td>NP (3.5 mm)</td></tr>
<tr><td>4.3, 5.0</td><td>RP (3.9 mm)</td></tr>
<tr><td>5.5</td><td>WP (5.1 mm)</td></tr>
<tr><td rowspan="4">NobelReplace® Trilobe</td><td>3.5</td><td>NP (3.5 mm)</td></tr>
<tr><td>4.3</td><td>RP (4.3 mm)</td></tr>
<tr><td>5.0</td><td>WP (5.0 mm)</td></tr>
<tr><td>6.0</td><td>6.0 (6.0 mm)</td></tr>
</table></td></tr>
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Table of Substantial Equivalence– Indications for Use Statements

<table>
<tr><th></th><th>Indications for Use Statement</th></tr>
<tr><td></td><td>
<table>
<tr><td rowspan="3">Nobel Brånemark System®</td><td>3.3</td><td>NP (3.5 mm)</td></tr>
<tr><td>3.75, 4.0</td><td>RP (4.1 mm)</td></tr>
<tr><td>5.0</td><td>WP (5.1 mm)</td></tr>
<tr><td rowspan="2">Osstem TS</td><td>3.5</td><td>Mini (2.8 mm)</td></tr>
<tr><td>4.0, 4.5, 5.0, 6.0, 7.0</td><td>Regular (3.35 mm)</td></tr>
<tr><td rowspan="2">Straumann® Bone Level</td><td>3.3</td><td>NC (3.3 mm)</td></tr>
<tr><td>4.1/4.8</td><td>RC (4.1/4.8 mm)</td></tr>
<tr><td rowspan="3">Straumann® Tissue Level</td><td>3.3</td><td>NNC (3.5 mm)</td></tr>
<tr><td>3.3, 4.1, 4.8</td><td>RN (4.8 mm)</td></tr>
<tr><td>4.8</td><td>WN (6.5 mm)</td></tr>
<tr><td rowspan="3">Zimmer Screw Vent®/ Tapered Screw-Vent®</td><td>3.3, 3.7, 4.1</td><td>3.5 mm</td></tr>
<tr><td>4.7</td><td>4.5 mm</td></tr>
<tr><td>6.0</td><td>5.7 mm</td></tr>
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<tr><td></td><td></td></tr>
<tr><td>Additional Predicate Devices</td><td></td></tr>
<tr><td>K123988
AnyOne™ Internal Implant System
MegaGen Implant Co., Ltd.</td><td>The AnyOne™ Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than Ø6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading</td></tr>
<tr><td>K182448
AnyRidge Octa 1 Implant System
MegaGen Implant Co., Ltd.</td><td>The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols:
- Delayed loading.
- Immediate loading when good primary stability is achieved and with appropriate occlusal loading
Larger implants are dedicated for the molar region.</td></tr>
<tr><td>K140091
Xpeed AnyRidge Internal Implant System
MegaGen Implant Co., Ltd.</td><td>The Xpeed AnyRidge Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient’s chewing function. Smaller implants (less than Ø6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.</td></tr>
<tr><td>K140728
Dental Implants and Abutments
Ditron Precision Ltd [Ditron Dental Ltd.]</td><td>Ditron's Dental Implants and Abutments are indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient’s chewing function.
Two stage: MPI, CPI models
One stage: OPI model
One stage and One piece OPI 3.3 and 3.0 mm diameter implants are intended only for the incisors and cuspids of the maxilla and mandible. They are also indicated for denture stabilization using multiple implants.
Two stage and One stage implants for temporary or long-term use: MPI, CPI, OPI are self-tapping titanium threaded screws indicated for long term intra bony applications. They permit immediate splint stability and long-term fixation of new or existing crown, bridge and prosthesis and protection of graft sites.
MPI, CPI and OPI designs are indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.
MPI, CPI and OPI are indicated for immediate loading in single tooth restorations when good primary stability is achieved with appropriate occlusal loading.
The 30-degree multi-unit abutments must be used within 45 degrees of parallelism for a splinted restoration. The 17-degree multi-unit abutments must be used within 32 degrees of parallelism for a splinted restoration.</td></tr>
</table>

Table of Substantial Equivalence – Technological Characteristics

Feature	**Subject Device**	**Primary Predicate Device**	**Predicate Device**	**Predicate Device**
	K203240	K191986	K123988	K182448
	AccelX™ Abutments	DESS Dental Smart Solutions	AnyOne™ Internal Implant System	AnyRidge Octa 1 Implant System
	Integrated Dental Systems LLC	Terrats Medical SL	MegaGen Implant Co., Ltd	MegaGen Implant Co., Ltd
Product Code	NHA	NHA	DZE, NHA	DZE, NHA
Reason for Predicate/ Reference Device	n/a	Indications for Use; CAD-CAM abutments; Referenced sterilization and biocompatibility	Designs and dimensions for Cover Screws, Healing Abutments, Temporary Abutments, Prepable Straight Abutments, Angled Abutments, and Titanium Base Abutments	Designs and dimensions Castable Base Abutment Co-Cr-Mo Alloy and Multi-Unit Abutments
Abutment Designs				
Cover Screws	Coronal Ø 3.5 mm CH*: 1 mm – 2.8 mm		Diameters 3.5 mm – 10 mm CH: 1 mm – 7 mm Prosthetic Platform Ø: 4 mm – 7 mm Post Height: 5.5 mm – 10 mm Angulation: 15°, 25°	
Healing Abutments	Coronal Ø 4 mm – 10 mm CH: 3 mm – 7 mm			
Temporary Abutments	Prosthetic Platform Ø: 4 mm CH:2 mm Prosthetic Post: 10 mm			
Prepable Straight Abutments	Prosthetic Platform Ø: 4 mm – 7 mm CH: 2 mm – 5 mm Prosthetic Post: 5.5 mm or 7.0 mm			
Angled Abutments	Prosthetic Platform Ø: 4 mm – 7 mm CH: 2 mm – 5 mm Prosthetic Post: 7.0 mm Angle: 15°, 25°			
Castable Base Abutments- Co-Cr-Mo Alloy	Prosthetic Platform Ø: 3.8 mm Angle of final design: 0°			Prosthetic Platform Ø: 3.8 mm
Multi-Unit Abutments	Prosthetic Platform Ø: 4.8 mm CH: 1.3 mm – 4.5 mm Angle: 0°, 17°, 30°			Prosthetic Platform Ø: 4.8 mm CH: 1.3 mm – 4.3 mm Angle: 0°, 17°, 30°
Cylinders (copings) for Multi-unit Abutments Material Prosthetic diameter Overall height	Material: Ti-6Al-4V alloy Prosthetic diameter: 4.8 mm Overall height: 12 mm			*Not in 510(k) Summary* Material: Ti-6Al-4V alloy Prosthetic diameter: 4.8 mm Overall height: 12 mm
Titanium Base Abutments	Post Height: 4.5 mm or 6 mm CH: 0.6 mm and 1.5 mm Angle of final design: 0°	Ti Base	Post Height: 4.5 mm, 6 mm, 8 mm CH: 0.6 mm, 1.5 mm, 3.0 mm, 4.0 mm	
Titanium Blank Abutments	Overall Milling Ø: 10 mm or 12 mm Angle of final design: 0° - 30°	Overall Milling Ø: 10 mm or 14 mm		
Abutment-Implant Interface	Internal Connection	Internal Connection	Internal Connection	Internal Connection
Abutment Screws				
Designs	Abutment Multi Post Screw Multi-Unit Abutment Screw Multi-Unit Prosthetic Screw	Abutment Screw	*Not in 510(k) Summary*	Abutment Screw Multi-Unit Abutment Screw
Materials	Ti-6Al-4V	Ti-6Al-4V with DLC coating	*Not in 510(k) Summary*	*Not in 510(k) Summary*

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Feature	Subject Device	Primary Predicate Device	Predicate Device	Predicate Device
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	AccelX™ Abutments	DESS Dental Smart Solutions	AnyOne™ Internal Implant System	AnyRidge Octa 1 Implant System
	Integrated Dental Systems LLC	Terrats Medical SL	MegaGen Implant Co., Ltd	MegaGen Implant Co., Ltd
Abutment Materials	Titanium alloy (ASTM F136)	Titanium alloy (ASTM F136)	Titanium alloy (ASTM F136)	Ti-6AI-4V-ELI (ASTM F136)
	Co-Cr-Mo alloy (ASTM F1537)	Co-Cr-Mo alloy (ASTM F1537)		Co-Cr-Mo alloy (ASTM F1537)
	Zirconia (ISO 13356)	Zirconia (ISO 13356)		
How Provided – Prosthetic Components				
Sterility	Non-Sterile	Non-Sterile	Sterile	Sterile
Sterilization Method	Moist Heat	Moist Heat	Gamma Sterilization	Gamma Sterilization
Usage	Single patient, single-use	Single patient, single-use	Single patient, single-use	Single patient, single-use

* CH=Cuff height (gingival height)