November 6, 2024

Biotech Dental LLC
% Chris Brown
Manager
Aclivi, LLC
3250 Brackley Drive
Ann Arbor, Michigan 48105

Re: K242261
Trade/Device Name: Accelx Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: August 1, 2024
Received: November 5, 2024

Dear Chris Brown:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242261

Device Name
Accelx Implant System

Indications for Use *(Describe)*
Accelx Implant System implants are indicated for use in partially or fully edentulous patients to support maxillary and mandibular single-unit, multiple-unit, and overdenture dental restorations. Accelx Implant System implants are indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Implant diameters larger than 6.0 mm are dedicated for the molar region and are indicated for delayed loading.

Accelx Implant System implants are compatible with Accelx Implant System abutments.

Accelx Implant System implants are compatible with MegaGen AnyRidge Internal Implant System titanium abutments as listed below.

Implant System Compatibility	Platform Diameter, mm	Maximum Angulation
MegaGen AnyRidge Internal Implant System	3.5, 4.0, 4.25, 5.0	25°

Accelx Implant System cover screws are compatible with MegaGen AnyRidge Internal Implant System implant 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, 4.0
	5.4	3.5, 4.25
	5.9	3.5, 4.25
	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
K242261
Accelx Implant System
November 5, 2024

ADMINISTRATIVE INFORMATION

Manufacturer Name	Biotech Dental LLC 145 Cedar Ln, Suite 205 Englewood, NJ 07631 Telephone: +1 (201) 676-2456 Fax: n/a
Official Contact	David Singh, CEO
Email:	david.singh@biotechdentalusa.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Accelx Implant System
Common Name:	Implant, Endosseous, Root-Form
Regulation Name:	Endosseous dental implant
Regulation Number:	21 CFR 872.3640
Device Class:	Class II
Product Code:	DZE, NHA
Review Panel:	Dental Products Panel
Reviewing Branch:	Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1) Dental Devices (DHT1B)

PREDICATE DEVICE INFORMATION

The devices within this submission are substantially equivalent in indications, intended use and technological characteristics to the following Predicate device. The Subject device shares technological characteristics with the following Reference devices.

510(k)	Predicate Device Name	Company Name
K123870	Xpeed AnyRidge Internal Implant System	MegaGen Implant Co., Ltd.
510(k)	**Reference Device Name**	**Company Name**
K203240	Accelx Abutments	Biotech Dental LLC
K233231	Dental Implants and Abutments	Ditron Precision Ltd.
K110955	AnyRidge Internal Implant System	MegaGen Implant Co., Ltd.

INDICATIONS FOR USE

Accelx Implant System implants are indicated for use in partially or fully edentulous patients to support maxillary and mandibular single-unit, multiple-unit, and overdenture dental restorations. Accelx Implant System implants are indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Implant diameters larger than 6.0 mm are dedicated for the molar region and are indicated for delayed loading.

Accelx Implant System implants are compatible with Accelx Implant System abutments.

Accelx Implant System implants are compatible with MegaGen AnyRidge Internal Implant System titanium abutments as listed below.

Implant System Compatibility	Platform Diameter, mm	Maximum Angulation
MegaGen AnyRidge Internal Implant System	3.5, 4.0, 4.25, 5.0	25°

Accelx Implant System cover screws are compatible with MegaGen AnyRidge Internal Implant System implant 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, 4.0
	5.4	3.5, 4.25
	5.9	3.5, 4.25
	6.4	5.0
	6.9	5.0
	7.4	5.0
	7.9	5.0
	8.4	5.0

DEVICE DESCRIPTION

The Accelx Implant System comprises Accelx dental implants, Accelx cover screws, and Accelx abutments previously cleared in K203240. The Accelx Implant System is compatible with the MegaGen AnyRidge Internal Implant System, regardless of the implant platform; this compatibility is due to the internal taper connection.

Accelx dental implants have an internal taper abutment interface connection and an internal hexagonal feature for abutment anti-rotation and instrument attachment. The internal threaded section is for mating to the corresponding Accelx cover screws, abutments and screws previously cleared in K203240, and MegaGen AnyRidge Internal Implant System restorative devices.

Accelx dental implants are provided in ten body diameters ranging from 4.0 mm to 8.4 mm, and in total lengths ranging from 7.7 mm to 14.2 mm. Implants with a body diameter of 4.0 mm and 4.4 mm have a platform diameter of 3.5 mm. Implants with a body diameter of 4.9 mm have a platform diameter of 3.5 mm or 4.0 mm. Implants with a body diameter of 5.4 mm to 5.9 mm have a platform diameter of 3.5 mm or 4.25 mm. Implants with a body diameter of 6.4 mm to 8.4 mm have a platform diameter of 5.0 mm. The implants are manufactured from titanium alloy conforming to ASTM F136. The endosseous surface of the implant is aluminum oxide-blasted and acid-etched from the implant collar to the apex. All Accelx dental implants are intended to be placed 0.5-1.0 mm sub crestal.

Accelx cover screws are provided with a coronal diameter of 3.5 mm in overall lengths of 5.7 mm, 6.5 mm, and 7.5 mm and gingival heights (cuff heights) of 0.8 mm, 1.6 mm, and 2.6 mm, respectively. The cover screws are manufactured from titanium alloy confirming to ASTM F136 and anodized. The cover screws are single use only. The smallest cover screw is provided sterile within the Subject device implant packaging. They are also provided individually as replacement or alternative parts in the same non-sterile packaging configuration as cleared in K203240.

Non-clinical Performance Data

The Acclex implants and cover screws were evaluated and tested as recommended in the FDA guidance document, *Root Form Endosseous Dental Implants and Endosseous Dental Implant Abutments* (issued May 12, 2004).

Non-clinical data submitted to demonstrate substantial equivalence included: evaluation of the modified surface of the dental implant, biocompatibility testing according to ISO 10993-1, bacterial endotoxin testing, sterilization validations,

shelf-life testing, a magnetic resonance information (MRI) safety assessment, reverse engineering of OEM implants to confirm OEM compatibility, and static and compression fatigue testing according to ISO 14801.

Modified Surfaces

Implant surfaces were evaluated after media blasting and cleaning by scanning electron microscope (SEM) and energy dispersive X-ray spectroscopy (EDS) characterization meeting acceptance criteria.

Biocompatibility

Cytotoxicity testing according to ISO 10993-5, bacterial endotoxin testing according to ANSI/AAMI ST72, USP <161> and USP <85> and material mediated pyrogenicity per USP <151> Pyrogen Test was performed on representative devices.

Sterilization

Gamma sterilization validation was performed according to ISO 11137-2 and ISO 13004 was performed for implants; moist heat (steam) sterilization according to ISO 17665-1 and ISO 17665-2 for non-sterile cover screws.

Magnetic Resonance Imaging Safety

Non-clinical worst-case MRI review was performed to evaluate the subject device components in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan, *"Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices."* Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the entire system including all variations (all compatible implant bodies, abutments, and fixation screws) and material composition. rationale addressed parameters per the FDA guidance Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment, including magnetically induced displacement force and torque.

Reverse Engineering

Reverse engineering of the MegaGen AnyRidge Internal Implant system abutment connection was performed to demonstrate physical compatibility. This testing was performed on OEM implant bodies, OEM abutments, and OEM abutment screws.

Mechanical Performance

Mechanical performance testing of the Accelx Implant System was performed in conformance to ISO 14801:2016, *Dentistry – Implants – Dynamic loading test for Endosseous Dental Implants.* The worst-case scenario was chosen based on FDA guidance document *Root Form Endosseous Dental Implants and Endosseous Dental Implant Abutments*. The fatigue limit data demonstrated that constructs of the previously cleared Accelx abutments (K203240) and previously cleared MegaGen AnyRidge Internal Implant System OEM abutments in combination with Accelx implants have sufficient strength for their intended use.

The results of the non-clinical testing demonstrate that the Subject device is suitable for the intended use and is the same or highly similar to the Predicate device.

No clinical or animal testing data is included in this premarket notification.

Equivalence to Marketed Devices

Overall, the Subject device is substantially equivalent in indications and design principles to the sponsor's Predicate and Reference devices listed above. Provided at the end of this summary are tables comparing the Indications for Use Statements and the technological characteristics of the Subject, Predicate device, and Reference devices.

The Subject device Accelx dental implants are compatible with the Accelx Abutments cleared in K203240 and together complete the Accelx Implant System.

Indications for Use Statement

The Subject device Indications for Use Statement (IFUS) is similar to that of the K123870 Predicate and the K110955 and K233231 Reference devices. Slight differences in the language of the IFUS do not affect the intended use as an endosseous dental implant for use with dental implant abutments and screws for support of a prosthesis to restore chewing function.

Minor differences between the IFUS for the Subject device and the K123870 Predicate include the following: the Subject device IFUS includes the term "single-unit, multiple-unit, and overdenture dental restorations" and the Predicate IFUS uses alternative terminology "Crown, bridges, and overdentures"; the Subject device IFUS includes references to compatible OEM implant systems and the Predicate IFUS does not include OEM compatibility; the Subject device IFUS states "Implant diameters larger than 6.0 mm are dedicated for the molar region and are indicated for delayed loading" and the predicate IFUS states more generically "Larger implants are dedicated for the molar region and are indicated for delayed loading"; and differences in tradenames. These same differences apply to comparisons of the Subject device to the K110955 Reference device. These minor differences do not raise new questions of safety or effectiveness because both IFUS express equivalent intended use to provide support for prosthetic devices to restore chewing function, expressed equivalently using different specific wording.

Minor differences between the Subject device and the K233231 Reference device include the following: differences in tradename; the Subject device IFUS includes references to compatible OEM implant systems and the Reference IFUS does not include OEM compatibility; the Reference device IFUS distinguishes models for one stage and two stage restorations and the Subject device IFUS distinguishes implant diameters and lengths for immediate and delayed loading; and the Reference IFUS includes indications specific to the use of angled multi-unit abutments and the Subject device IFUS does not. These minor differences do not raise new questions of safety or effectiveness as both IFUS express equivalent intended use to provide support for prosthetic devices to restore chewing function, expressed equivalently using different specific wording.

The Subject device IFUS includes a reference to OEM prosthetic components the Subject device dental implants are compatible with. Unless an endosseous dental implant is a one-part implant including an inherent support structure for a definitive restoration, dental implants are used in conjunction with compatible abutments. Normally these abutments are not specifically listed in the IFUS. Since the Subject device implants are compatible with another OEM abutments, the critical design parameters of those OEM abutments are listed in the IFUS. This minor difference in IFUS language does not raise new questions of safety or effectiveness as the IFUSs express equivalent intended use to provide support for prosthetic devices to restore chewing function, expressed equivalently using different specific wording and is supported through non-clinical bench testing.

Technological Characteristics

Accelx Implants

Predicate Device K123870, Xpeed AnyRidge Internal Implant System

The Subject device Accelx dental implants are similar in designs and sizes to the Xpeed AnyRidge Internal Implant System implants cleared in the K123870 Predicate device. The Subject device implants also the same internal tapered abutment interface connection and internal hexagonal feature for abutment anti-rotation and instrument attachment.

The Subject device and K123870 Predicate implants are provided in the same body diameters ranging from 4.0 mm to 8.4 mm. Both the Subject device implants and the K123870 Predicate device implants with body diameters of 4.0 mm to 5.9 mm are available with a platform diameter of 3.5 mm. The Subject device and the K123870 Predicate device implants

with body diameters of 4.9 mm are also available with a platform diameter of 4.0 mm. The Subject device and the K123870 Predicate device implants with body diameters of 5.4 and 5.9 mm are also available with a platform diameter of 4.25 mm. Similarly, both the Subject device and K123870 Predicate device implants with body diameters of 6.4 mm to 8.4 mm have a platform diameter of 5.0 mm. The Subject device implant lengths range from 7.7 mm to 14.2 mm and are encompassed by the K123870 Predicate device implants provided in lengths ranging from 6.2 mm to 17.2 mm. The Subject device implants are fabricated from a similar titanium material and have a similar modified surface treatment as the K123870 Predicate device. The Subject device implants have the same sterilization method and single-patient, single-use usage as the K123870 Predicate device.

Reference Device K203240, Accelx Abutments
The K203240 Reference device is included to support the previously cleared Accelx abutments which are compatible with the Subject device implants.

Reference Device K233231, Dental Implants and Abutments
The Subject device implants are similar in body diameter, platform diameter and length to the K233231 Reference device implants.

The Subject device implants are fabricated from the same ASTM F136 titanium alloy and have the same alumina grit blasting and acid etching surface treatment, and the same sterilization process as the K233231 Reference device implants. The Subject device implants and cover screws have the same single-patient, single-use usage as the K233231 Reference device. Additionally, both the Subject device and K233231 Reference device cover screws are color anodized.

Reference Device K110955, AnyRidge Internal Implant System
The Subject device cover screws have the same coronal diameter and gingival heights as the K110955 Reference device cover screws and are manufactured from the same ASTM F136 titanium alloy. Additionally, both the Subject device and K110955 Reference device cover screws are color anodized.

For Subject device cover screws provided with the implants, the Subject device cover screws are supplied sterile, the same as the K110955 Reference device. Unlike the K110955 Reference device, the Subject device cover screws supplied as replacements or alternate sizes are not delivered sterile. However, they are the cover screws are intended to be used sterile and the sponsor has provided a validated moist-heat sterilization process in device labeling.

Reverse engineering and compatibility analysis was performed to validate physical compatibility of the Subject device implants with the K123870 Predicate and K110955 Reference device Anyridge Internal Implant System implant/abutment connections. Additionally, fatigue testing according to ISO 14801, *Dentistry — Implants — Dynamic loading test for endosseous dental implants* was performed to validate compatibility.

Minor differences in technological characteristics the Subject and the Predicate and Reference devices do not affect substantial equivalence. These minor differences do not impact safety or effectiveness as these differences are mitigated by bench performance testing.

CONCLUSION
Overall, the Indications for Use statements are similar, differing in specific wording, but have the same intended use to provide prosthetic support for dental restorations. The Subject device additional language regarding compatibility is supported through bench performance testing.

Overall, the Technological Characteristics of the Subject device are highly similar or the same as the Predicate and Reference devices. Any minor differences in Technological Characteristics are supported through bench performance testing.

The Accelx implants and cover screws are substantially equivalent in indications and design principles to the Predicate device and Reference devices listed above. Provided at the end of this summary is a table comparing the Indications for Use Statements and Technological Characteristics of the Accelx Implant System, the Predicate device and the Reference devices.

Substantial Equivalence - Indications for Use Statement

<table>
<tr><th>Subject Device
Accelx Implant System
Biotech Dental LLC</th><th>Predicate Device
Xpeed AnyRidge Internal Implant System
MegaGen Implant Co., Ltd.
K123870</th><th>Reference Device
Dental Implants and Abutments
Ditron Precision Ltd.
K233231</th><th>Reference Device
AnyRidge Internal Implant System
MegaGen Implant Co., Ltd.
K110955</th></tr>
<tr>
<td>Accelx Implant System implants are indicated for use in partially or fully edentulous patients to support maxillary and mandibular single-unit, multiple-unit, and overdenture dental restorations. Accelx Implant System implants are indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Implant diameters larger than 6.0 mm are dedicated for the molar region and are indicated for delayed loading.

Accelx Implant System implants are compatible with Accelx Implant System abutments.

Accelx Implant System implants are compatible with MegaGen AnyRidge Internal Implant System titanium abutments as listed below.
<table>
<tr><th>Implant System Compatibility</th><th>Platform Diameter, mm</th><th>Maximum Angulation</th></tr>
<tr><td>MegaGen AnyRidge Internal Implant System</td><td>3.5, 4.0, 4.25, 5.0</td><td>25°</td></tr>
</table>
Accelx Implant System cover screws 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, 4.0</td></tr>
<tr><td>5.4</td><td>3.5, 4.25</td></tr>
<tr><td>5.9</td><td>3.5, 4.25</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>
<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>
<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, ULT, API and CPI models
• One stage: OPI and TPI models

The 3.3 and 3.0mm diameter models for One stage OPI and TPI, Two stage MPI, Two stage and API 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, ULT, API, CPI, OPI and TPI 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, ULT, API, CPI, OPI and TPI designs are indicated for immediate loading (except for MPI and API in 6.0mm length) when good primary stability is achieved and with appropriate occlusal loading.

MPI, ULT, API, CPI, OPI and TPI are indicated for immediate loading (except for MPI and API in 6.0mm length) in single tooth restorations when good primary stability is achieved with appropriate occlusal loading.

The 30° multi-unit abutments must be used within 45 degrees of parallelism for a splinted restoration.

The 17° multi-unit abutments must be used within 32 degrees of parallelism for a splinted restoration.</td>
<td>The 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>
</table>

Table A. Substantial Equivalence - Indications for Use Statement

Comparison of Technological Characteristics

Comparison	**Subject Device** Accelx Implant System Biotech Dental LLC	**Predicate Device** Xpeed AnyRidge Internal Implant System MegaGen Implant Co., Ltd. K123870	**Reference Device** Accelx Abutments Biotech Dental LLC K203240	**Reference Device** Dental Implants and Abutments Ditron Precision Ltd. K233231	**Reference Device** AnyRidge Internal Implant System MegaGen Implant Co., Ltd. K110955	**Comparison**
Product Code	DZE, NHA	DZE, NHA	NHA	DZE, NHA	DZE, NHA	***Same***
Regulation	872.3640	872.3640	872.3630	872.3640	872.3640	***Same***
Intended Use	Functional and esthetic rehabilitation of partially or fully edentulous maxilla and mandible to restore chewing function.	Functional and esthetic rehabilitation of partially or fully edentulous maxilla and mandible to restore chewing function.	Functional and esthetic rehabilitation of partially or fully edentulous maxilla and mandible to restore chewing function.	Functional and esthetic rehabilitation of partially or fully edentulous maxilla and mandible to restore chewing function.	Functional and esthetic rehabilitation of partially or fully edentulous maxilla and mandible to restore chewing function.	***Same***
Reason for Predicate/Reference	Not Applicable	OEM Abutment Compatibility; Implant Designs	Previously cleared abutments compatible with Subject device implants	Implant material and surface treatment, anodized cover screws	OEM Compatibility, Cover Screw Designs	***n/a***
Implants						
Prosthetic Interface Connection	Internal Hex	Internal Hex	n/a	Internal Hex	n/a	***Same***
Body/Platform Diameter, mm	Implant Body Diameter: 4.0, 4.4, 4.9, 5.4, 5.9 — Platform Diameter: 3.5 Implant Body Diameter: 4.9 — Platform Diameter: 4.0 Implant Body Diameter: 5.4, 5.9 — Platform Diameter: 4.25 Implant Body Diameter: 6.4, 6.9, 7.4, 7.9, 8.4 — Platform Diameter: 5.0	Implant Body Diameter: 4.0, 4.4, 4.9, 5.4, 5.9 — Platform Diameter: 3.5 Implant Body Diameter: 4.9 — Platform Diameter: 4.0 Implant Body Diameter: 5.4, 5.9 — Platform Diameter: 4.25 Implant Body Diameter: 6.4, 6.9, 7.4, 7.9, 8.4 — Platform Diameter: 5.0	n/a	Implant Body Diameter: 3.5, 3.75 — Platform Diameter: 4.0 Implant Body Diameter: 4.2, 5.0 — Platform Diameter: 4.25 Implant Body Diameter: 6.4, 6.9, 7.4, 7.9, 8.4 — Platform Diameter: 5.0	n/a	***Same – Predicate*** ***Highly Similar - Reference***
Body diameter and Lengths, mm	Implant Body Diameter: 4.0, 4.4, 4.9, 5.4, 5.9 — Lengths: 7.7, 9.2, 10.7, 12.2, 14.2 Implant Body Diameter: 6.4, 6.9, 7.4, 7.9, 8.4 — Lengths: 6.4, 7.9, 9.4, 10.9, 12.4	Implant Body Diameter: 4.0, 4.4, 4.9, 5.4, 5.9 — Lengths: 6.2, 7.7, 9.2, 10.7, 12.2, 14.2 Implant Body Diameter: 6.4, 6.9, 7.4, 7.9, 8.4 — Lengths: 6.4, 7.9, 9.4, 10.9, 12.4, 14.4	n/a	Implant Diameter: 3.5, 3.75 — Lengths: 8.0, 10, 11, 13, 16 Implant Diameter: 4.2, 5.0 — Lengths: 8.0, 10, 11, 13, 16	n/a	***Highly Similar*** *Subject device dimensions encompassed by Predicate and Reference Devices*
Implant Material	Titanium Alloy (ASTM F136)	CP Ti Grade 4 (ASTM F67)	n/a	Titanium Alloy (ASTM F136)	n/a	***Similar – Predicate*** ***Same – K233231 Reference device***
Implant Surface Treatment	Alumina Grit blasting and Acid Etching	Sand-blasted, Large grit, Acid-etched (SLA)	n/a	Alumina Grit blasting and Acid Etching Color anodization of Tissue-Level Neck	n/a	***Highly Similar – Predicate*** ***Same – K233231 Reference device (body below the neck)***
Sterility	Gamma Irradiation	Gamma Irradiation	n/a	Gamma Irradiation	n/a	***Same***
Usage	Single Patient, Single-Use	Single Patient, Single-Use	n/a	Single Patient, Single-Use	n/a	***Same***
Cover Screws						
Material	Anodized Titanium Alloy (ASTM F136)	n/a	Anodized Titanium Alloy (ASTM F136)	Anodized Titanium Alloy (ASTM F136)	Anodized Titanium Alloy (ASTM F136)	***Same as K110955 Reference Device***
Coronal Diameter, mm	3.5	n/a	3.5	4.8	3.5	***Same as K110955 Reference Device***
Cuff/Gingival Height, mm	0.8, 1.6, 2.6	n/a	0.8, 1.6, 2.6	3.5, 4.5, 5.5	0.8, 1.6, 2.6	***Same as K110955 Reference Device***
Sterility	Supplied with implant – Sterile Supplied as Replacement/Alternate - Non-Sterile	n/a	Supplied with implant – Sterile Supplied as Replacement/Alternate - Non-Sterile	Sterile	Sterile	***Highly Similar***
Sterilization Method	Supplied with implant – Gamma Irradiation Supplied as Replacement/Alternate - Moist Heat	n/a	Supplied with implant – Gamma Irradiation Supplied as Replacement/Alternate - Moist Heat	Gamma Irradiation	Gamma Irradiation	***Similar***
Usage	Single patient, single use	n/a	Single patient, single use	Single Patient, Single-Use	Single patient, single use	***Same as Reference Devices***

Table B. Substantial Equivalence – Technological Characteristics