June 18, 2026

MegaGen Implant Co., Ltd.
Hyo-Eun Lee
Official Correspondent
45, Secheon-ro 7-gil, Dasa-eup, Dalseong-gun
Daegu, 42921
REPUBLIC OF KOREA

Re: K251232
Trade/Device Name: MegaGen Zygoma Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: May 10, 2026
Received: May 14, 2026

Dear Hyo-Eun Lee:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251232

Please provide the device trade name(s).

MegaGen Zygoma Dental Implant System

Please provide your Indications for Use below.

Zygoma Dental Implant system is intended to replace missing tooth/teeth by surgical installation in the zygoma region for supporting prosthetic devices that may aid in restoring the patient's chewing function. The procedure can be accomplished in a one-stage or two-stage surgical operation. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading. The Dental implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.
Zygomatic Dental Implants are intended to be implanted in the upper jaw arch to provide support for fixed or removable prosthetic devices in patients with partially or fully edentulous maxilla.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of 21 CFR Part 807.92.

Date: June 09, 2026

1. Applicant / Submitter

MegaGen Implant Co., Ltd.
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2. Submission Correspondent

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3. Device

- Trade Name: MegaGen Zygoma Dental Implant System
- Common Name: Endosseous Dental Implant
- Classification Name: Implant, Endosseous, Root-Form
- Classification Regulation: 872.3640
- Primary Product Code: DZE
- Secondary Product Code: NHA

4. Predicate Device

· **Primary Predicate Device:**
K151909 - Noris Medical Zygomatic Dental Implant System

· **Reference Device:**
K192651- ZAGA Zygomatic System
K232099 - Neodent Implant System - GM Zygomatic Implants System
K190491 - Blue Sky Bio Zygomatic Implant System
K212785 - GM Helix LG Neodent Implant System
K160119 - NobelSpeedy® Groovy
K241972- BLUEDIAMOND IMPLANT
K210356 - Noris Medical Dental Implant System
K242030 - MegaGen Dental Implant Abutment
K233450 - MegaGen Dental Implant Abutment - Scan Healing Abutment; Temporary Abutment; Temporary Cylinder; Comfort Cap; Healing Cap; Healing Cap Screw; Milling Abutment; EZ Post Abutment; Extra EZ Post Abutment; EZ Post Cylinder; ZrGEN Abutment; Multi-unit Abutment; Multi-unit Angled Abutment; AXA Abutment (Straight); AXA Abutment (Angled); Abutment Screw; Cylinder Screw; Crown Screw
K190958 - Neodent Implant System
K122231 - XPEED ANY RIDGE INTERNAL IMPLANT SYSTEM

K182448 - AnyRidge Octa 1 Implant System
K110955 - ANYRIDGE INTERNAL IMPLANT SYSTEM
K220562 - TiGEN Abutment, ZrGEN Abutment and Scan Healing Abutment
K150537 - MiNi Internal Implant System
K203554 - AnyOne External Implant System

5. Description

- **ZYGOMA IMPLANT (BD/AR/ AO ZYGOMA IMPLANT)**
  The ZYGOMA IMPLANT is intended to be implanted in the upper jaw arch to provide support for fixed or removable dental prostheses in partially edentulous or full arch prostheses. It is for immediate function when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. It is made of CP Ti Grade 4 with the surface treated by SLA method. The proposed MegaGen Zygoma Implants (BD, AR, AO models) are limited in use to ZAGA Class 4 only.

  The dimensions of **IMPLANT** are follows:

Product	Dimensions (Diameter x Length)
BD ZYGOMA IMPLANT	Ø 4.2 x 30, 32.5, 35, 37.5,40, 42.5, 45, 47.5, 50, 52.5, 55, 57.5 mm
AR ZYGOMA IMPLANT	Ø 4.2 x 30, 32.5, 35, 37.5,40, 42.5, 45, 47.5, 50, 52.5, 55, 57.5 mm
AO ZYGOMA IMPLANT	Ø 4.2 x 30, 32.5, 35, 37.5,40, 42.5, 45, 47.5, 50, 52.5, 55, 57.5 mm

- **AXA Abutment**
  The AXA Abutment is angled and is two-piece type, the lower part is intended to be placed on the endosseous dental implant and the top part is connected Healing Cap, Impression Coping or Cylinders, such as Temporary Cylinder and EZ Post Cylinder with the Screw to fabricate temporary or final prosthesis. It is made of Ti-6Al-4V-ELI and offered in anodizing gold. The 45˚, 52˚, 60˚ angles and two types (Hex type and Octa type) are available for use with ZYGOMA IMPLANT. The AXA Abutment is supplied non-sterile, to be sterilized by the user according to the IFU and intended for single use.

  The dimensions of **AXA Abutment** are follows:

Product	Compatibility Implant	Dimensions (Diameter x Cuff)
AXA Abutment	BD ZYGOMA IMPLANT	45˚: Ø 5.0 x 2.0, 3.0, 4.0, 5.0 mm 52˚: Ø 5.0 x 2.0mm 60˚: Ø 5.0 x 2.0mm
	AR ZYGOMA IMPLANT	45˚: Ø 5.0 x 2.0, 3.0, 4.0, 5.0 mm 52˚: Ø 5.0 x 2.0mm 60˚: Ø 5.0 x 2.0mm
	AO ZYGOMA IMPLANT	45˚: Ø 5.0 x 2.0, 3.0, 4.0, 5.0 mm 52˚: Ø 5.0 x 2.0mm 60˚: Ø 5.0 x 2.0mm

- **Multi-unit Abutment**
  The Multi-unit Abutment is angled and is two-piece type, the lower part is intended to be placed on the endosseous dental implant and the top part is connected Healing Cap, Impression Coping or Cylinders, such as Temporary Cylinder and CCM Cylinder with the Screw to fabricate temporary or final prosthesis. The Multi-unit Abutment is intended for both multiple unit restoration and single unit restoration. It is made of Ti-6Al-4V-ELI and offered in anodizing gold. The 45˚, 52˚, 60˚ angles and two types (Hex type and Octa type) are available for use with ZYGOMA IMPLANT. The Multi-unit Abutment is supplied non-sterile, to be sterilized by the user according to the IFU and intended for single use.

  The dimensions of **Multi-unit Abutment** are follows:

Product	Compatibility Implant	Dimensions (Diameter x Cuff height)
Multi-unit Abutment	BD ZYGOMA IMPLANT	45˚: Ø 4.8 x 2.0, 3.0, 4.0, 5.0 mm 52˚: Ø 4.8 x 2.0mm 60˚: Ø 4.8 x 2.0mm
	AR ZYGOMA IMPLANT	45˚: Ø 4.8 x 2.0, 3.0, 4.0, 5.0 mm 52˚: Ø 4.8 x 2.0mm 60˚: Ø 4.8 x 2.0mm
	AO ZYGOMA IMPLANT	45˚: Ø 4.8 x 2.0, 3.0, 4.0, 5.0 mm 52˚: Ø 4.8 x 2.0mm

		60˚: Ø 4.8 x 2.0mm

- **Abutment Screw**

The Abutment Screw is used for securing the abutment to the endosseous implant. It offers Hex type to select the right direction for connection. It is made of Ti-6AI-4V-EL. The Abutment Screw is supplied non-sterile, to be sterilized by the user according to the IFU and intended for single use.

The dimensions of **Abutment Screw** are follows:

Product	System	Dimensions (Diameter x Length)
Abutement Screw	BD ZYGOMA IMPLANT	Ø 1.9 x 2, 3, 4, 5, 6 mm
	AR ZYGOMA IMPLANT	Ø 1.95 x 2, 3, 4, 5, 6 mm
	AO ZYGOMA IMPLANT	Ø 1.95 x 2, 3, 4, 5, 6 mm

6. Indication for use

Zygoma Dental Implant system is intended to replace missing tooth/teeth by surgical installation in the zygoma region for supporting prosthetic devices that may aid in restoring the patient's chewing function. The procedure can be accomplished in a one-stage or two-stage surgical operation. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading. The Dental implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.

Zygomaic Dental Implants is intended to be implanted in the upper jaw arch to provide support for fixed or removable prosthetic devices in patients with partially or fully edentulous maxilla.

7. Basis for Substantial Equivalence

The MegaGen Zygoma Dental Implant System is substantially equivalent to the predicate device and reference devices in terms of indication for use, technical characteristic and function. They are made of the same material and have similar design, and it is not affecting substantial equivalence.
Based on the technological characteristic comparison tables below and test results provided in this submission, we conclude that the subject device is substantially equivalent to the predicate device.

Indication for Use Statement

	510K	Indication for Use Statement
Subject Device	K251232	Zygoma Dental Implant system is intended to replace missing tooth/teeth by surgical installation in the zygoma region for supporting prosthetic devices that may aid in restoring the patient's chewing function. The procedure can be accomplished in a one-stage or two-stage surgical operation. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading. The Dental implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants. Zygomaic Dental Implants is intended to be implanted in the upper jaw arch to provide support for fixed or removable prosthetic devices in patients with partially or fully edentulous maxilla.
Predicate Device	K151909	Noris Medical Dental Implants System is intended to replace missing tooth/teeth in either jaw for supporting prosthetic devices that may aid in restoring the patient's chewing function. The procedure can be accomplished in a one-stage or two-stage surgical operation. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Noris Medical Zygomatic Dental Implant System is intended to be implanted in the upper jaw arch to provide support for fixed or removable prosthetic devices in patients with partially or fully edentulous maxillae.
Reference Device	K192651	Southern Implants ZAGA Zygomatic System implants are intended to be implanted in the upper jaw arch to provide support for fixed dental prostheses in patients with partially or fully edentulous maxillae. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.
	K241972	The BLUEDIAMOND IMPLANT 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 in the following situations and with the clinical protocols: - Delayed loading - Immediate loading when good primary stability is achieved and with appropriate occlusal loading. For the BLUEDIAMOND IMPLANTS with a Thread Length of 5mm, It is indicated for fixed or removable reconstruction in situations of moderate to severely atrophic jawbone and with adequate bone quality that allows primary stability after implant insertion, where a longer implant cannot be placed due to limited vertical bone height. The recommended healing time before loading is between 10 to 12 weeks. It is specifically recommended for: - Fixed partial dentures/splinted units (one implant per unit) - Pontic cases in combination with at least one longer implant - Fully edentulous cases with at least one 5 mm Short Implant in combination with 2 longer implants in the anterior region and at least four total implants
	K212785	Blue Sky Bio Long Implant System is intended for surgical placement in the bone of the upper jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. Implants may be used with single-stage or two-stage procedures, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Blue Sky Bio Long implants can be placed bicortically in cases of reduced bone density. Blue Sky Bio Long implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants. Blue Sky Bio Long Implant System with a 45º angulation are indicated for surgical installation in the pterygoid region only, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function.
	K190958	The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. The Neodent GM Helix LG implants can be placed bicortically in cases of reduced bone density. The Neodent GM Helix LG implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants
	K160119	NobelSpeedy® Groovy implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient

		esthetics and chewing function. NobelSpeedy® Groovy implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique. Implants allow also for bi- cortical anchorage in cases of reduced bone density NobelSpeedy® Groovy implants 20, 22, 25 mm when placed in the maxilla are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.
	K210356	Noris Medical Dental Implants System is intended to replace missing tooth/teeth in either jaw for supporting prosthetic devices that may aid in restoring the patient's chewing function. The procedure can be accomplished in a one-stage or two-stage surgical operation. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Noris Medical Zygomatic Dental Implant System is intended to be implanted in the upper jaw arch to provide support for fixed or removable prosthetic devices in patients with partially or fully edentulous maxillae.
	K233450	The MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular 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 patients chewing function. All digitally designed abutments for use with ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture.
Substantial Equivalence Discussion		
Discussion The indications for use statement of the subject device is nearly identical to the primary predicate, except for minor changes in wording that do not affect the intended use. Both indicated for splinted restorations utilizing a minimum of two implants to support fixed or removable prosthetic in the maxilla and may be loaded immediately when good primary stability is achieved.		

MegaGen Zygoma Dental Implant

	Subject Device	Predicate Device	Reference Device	Reference Device	Reference Device	Reference Device	Reference Device
510k	K251232	K151909	K192651	K241972	K212785	K190958	K160119
Device Name	**MegaGen Zygoma Dental Implant**	**Noris Medical Zygomatic Dental Implant**	**Southern Implants ZAGA Zygomatic System implants**	**BLUEDIAMOND IMPLANT**	**Blue Sky Bio Dental Implant System - BIOILONG Implants**	**Neodent Implant System - GM Helix LG Implants**	**NobelSpeedy® Groovy**
Manufacturer	MegaGen Implant Co., Ltd.	Noris Medical Ltd.	Southern Implants (Pty) Ltd	MegaGen Implant Co., Ltd.	Blue Sky Bio, LLC	JJGC Industria e Comercio de Materiais Dentarios SA	Nobel Biocare AB
Patient Population	Edentulous or partially edentulous individuals	Edentulous or partially edentulous individuals	Unknown in 510k	Edentulous or partially edentulous individuals	Unknown in 510k	Unknown in 510k	Unknown in 510k
Material	CP Ti Grade 4 (ASTM F67)	Titanium alloy	Unalloyed titanium (ASTM F67) Grade 4, and UTS ≥ 900MPa (cold-worked)	CP Ti Grade 4 (ASTM F67)	Ti-6Al-4V ELI (ASTM F136)	CP Ti Grade 4 (ASTM F67)	CP Titanium
Implant Diameter (Ø, mm)	4.2	4.2	4.3	**Normal Thread:** 4.0, 4.4, 4.7 **Deep Thread:** 4.4, 4.8, 5.1	**Platform:** 3.5, NP (3.5) **Implant Body:** 3.7, 4.3, 5.0	3.75, 4.0	4.0
Length (mm)	30, 32.5, 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55, 57.5	30, 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55, 57.5	30, 32.5, 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5	· **Normal Thread** Ø 4.0: 7.0, 9.0 Ø 4.4: 5.0, 7.0, 9.0 Ø 4.7: 5.0, 7.0, 9.0 · **Deep Thread** Ø 4.4: 7.0, 9.0 Ø 4.8: 5.0, 7.0, 9.0 Ø 5.1: 5.0, 7.0, 9.0	20.0, 22.5, 25.0	20.0, 22.5, 25.0	20.0, 22.5, 25.0
Abutments°	45, 52, 60	45, 52*, 60* (*K210356)	55	30	Straight, 12, 17, 24, 30	Straight, 17, 30, 45* (*K190718)	45* (*K161598)
Surface Treatment	Sand-blasted, Large grit, Acid-etched (S.L.A) Machined collar	RBM (Resorbable Blast Media)	Grit-blasted	Sand-blasted, Large grit, Acid-etched (S.L.A) Machined collar	Grit blasted and acid etched	Machined, acid-etched NeoPoros surface.	Ti Unite
Thread Design	Tapered Screw type	Tapered Screw type	Unknown in 510k	Tapered Screw type	Unknown in 510k	Unknown in 510k	Unknown in 510k
Sterilization	Gamma irradiation	Gamma irradiation	Gamma irradiation	Gamma irradiation	Gamma irradiation	Gamma irradiation	Gamma irradiation
Clinical procedure	Immediate loading or for loading after a conventional healing period	Immediate loading or for loading after a conventional healing period	Immediate loading or for loading after a conventional healing period	Immediate loading or for loading after a conventional healing period	Immediate loading or for loading after a conventional healing period	Immediate loading or for loading after a conventional healing period	Immediate loading or for loading after a conventional healing period
Substantial Equivalence Discussion							

Discussion

The proposed subject device and Predicate/reference devices have common in all items in the comparison chart.

On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the predicate and reference devices.

AXA Abutment – Angled Type

	Subject Device	Predicate Device	Reference Device	Reference Device
510k	K251232	K151909	K210356	K233450
Device Name	AXA Abutment	Multi-unit abutment	Multi-unit abutment	**AXA Abutment(Angled)**
Manufacturer	MegaGen Implant Co., Ltd.	Noris Medical Ltd.	Noris Medical Ltd.	MegaGen Implant Co., Ltd.
Diameter (Ø, mm)	5.0	Unknown in 510k	Unknown in 510k	4.0, 5.0
Gingival Height (mm)	45°: 2.0, 3.0, 4.0, 5.0 52°, 60°: 2.0	45°: 2.0* (*refer to K210356)	45°: 3.0, 4.0, 5.0 52°,60°: 2.0	3.8, 5.8, 7.8 3.8, 5.8, 7.8 3.74, 5.74, 7.74
Angulation (˚)	45, 52, 60	45	45, 52, 60	20, 30
Connection Interface	Internal Hex, Internal Non-Hex, Internal Octa, Internal Non-Octa	Unknown	Internal Hex 3.75mm platform	Internal Hex, Internal Non-Hex, Internal Octa, Internal Non-Octa
Material	Ti-6Al-4V ELI (ASTM F136-13)	titanium alloy Ti 6Al 4V ELI	Titanium alloy	Ti-6Al-4V ELI (ASTM F136-13)
Surface Treatment	Machined, Anodizing	Anodizing	Anodizing	Machined, Anodizing
Single Use	Yes	Yes	Yes	Yes
Sterilization	Supplied non-sterile. Single use Steam sterilized before use	Unknown in 510K	Supplied non-sterile. Single use Steam sterilized before use	Non-sterile
Additional Post Component	EZ Post Cylinder	Unknown in 510K	Unknown in 510K	EZ Post Cylinder
Compatible Implant System	MegaGen Zygoma Dental Implant System	Noris Medical Dental implants System	Noris Medical Dental implants System	BLUEDIAMOND IMPLANT System XPEED AnyRidge interal Implant System AnyOne Internal Implant System
Substantial Equivalence Discussion				
Discussion The proposed subject device and Predicate/reference devices have common in all items in the comparison chart. And the fatigue test was performed as a representative of the worst-case model with angle. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the predicate and reference devices.				

Multi-unit Abutment

	Subject Device	Predicate Device	Predicate Device	Reference Device 1
510k	K251232	K151909	K210356	K233450
Device Name	Multi-unit Abutment	Multi-unit abutment	Multi-unit abutment	Multi-unit Angled Abutment
Manufacturer	MegaGen Implant Co., Ltd.	Noris Medical Ltd.	Noris Medical Ltd.	MegaGen Implant Co., Ltd.
Diameter (Ø, mm)	4.8	Unknown in 510k	Unknown	4.8
Gingival Height (mm)	45°: 2.0, 3.0, 4.0, 5.0 52°, 60°: 2.0	45°: 2.0* (*refer to K210356)	45°: 3.0, 4.0, 5.0 52°,60°: 2.0	5.3, 6.3, 5.24, 6.24
Angulation(°)	45, 52, 60	45	45, 52, 60	17, 30
Connection Interface	Internal Octa, Internal Non-Octa, Internal Hex, Internal Non-Hex,	Unknown	Internal Hex 3.75mm platform	Internal Octa, Internal Non-Octa, Internal Hex, Internal Non-Hex,
Material	Ti-6Al-4V ELI(ASTM F136-13)	titanium alloy Ti 6Al 4V ELI	Titanium alloy	Ti-6Al-4V ELI(ASTM F136-13)
Surface Treatment	Anodizing	Anodizing	Anodizing	Anodizing
Single Use	Yes	Yes	Yes	Yes
Sterilization	Supplied non-sterile. Single use Steam sterilized before use	Unknown in 510K	Supplied non-sterile. Single use Steam sterilized before use	Non-sterile
Compatible Implant System	MegaGen Zygoma Dental Implant System	Noris Medical Dental implants System	Noris Medical Dental implants System	BLUEDIAMOND IMPLANT System XPEED AnyRidge interal Implant System AnyOne Internal Implant System
Patient Population	Edentulous or partially edentulous individuals	Edentulous or partially edentulous individuals	Edentulous or partially edentulous individuals	Edentulous or partially edentulous individuals
Substantial Equivalence Discussion				
Discussion The proposed subject device and Predicate/reference devices have common in all items in the comparison chart. And the fatigue test was performed as a representative of the worst-case model with angle. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the predicate and reference devices.				

Abutment Screw

	Subject Device	Reference Device 1
510k	K251232	K233450
Device Name	Abutment Screw	**Abutment Screw**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Diameter (Ø, mm)	1.9, 1.95	2.0, 2.1, 2.2
Total Length (mm)	7.2~12.3	7.9 ~ 12.7
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)
Surface Treatment	Machined	Machined, Anodizing
Single Use	Yes	Yes
Sterilization	Non-sterile	Non-sterile
Compatible Implant System	BLUEDIAMOND IMPLANT System XPEED AnyRidge interal Implant System AnyOne Internal Implant System	BLUEDIAMOND IMPLANT System XPEED AnyRidge interal Implant System AnyOne Internal Implant System

Substantial Equivalence Discussion

Similarities

The subject device has the same characteristic for the followings compared to the reference devices.

- Indication for use, Design, Material, Surface Treatment, Single Use, Sterilization and Compatible Implant System

Differences

The subject device has the different characteristic for the followings compared to the reference device.

- Diameter

  The diameters of the subject device are smaller than the reference devices, but the variety of the size can be possible to operate more precise treatment to meet each patient's condition. Therefore, it does not cause a matter in substantial equivalence.

- Total Length

  The Total Length of the subject device is slightly different with the reference devices but it does not cause a matter in substantial equivalence since the size differences are very minor.

Discussion

The proposed Abutment Screw and Predicate device have common in all the terms in the comparison chart except Diameter and Total length. These differences are explained not affecting on device's fundamental functions and safety. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the Predicate device.

8. Summary of Non-Clinical Testing

The non-clinical testing data which are submitted, referenced, or relied on in this submission support demonstrating substantial equivalence.

Biocompatibility

The biocompatibility evaluation has been performed in accordance with International Standard ISO 10993-1 and ISO 10993-5. The subject device has same material composition, manufacturing process and patient contacting parts as our previously cleared device, XPEED AnyRidge Internal System (K122231), BLUEDIAMOND Implant System (K182448) and AnyRidge Internal Implant System (K110955).

Pyrogen and Endotoxin Test

The subject device will not be labeled as "non-pyrogenic", and the endotoxin testing will be conducted on every batch for the subject device with the testing limit of below 20 EU/device in accordance with the USP 43 <85> and <161>.

Sterilization validation and Shelf life

The ZYGOMA IMPLANTs are supplied in sterile state. Sterilization validating testing has been performed in accordance with ISO 11137 to verify the sterility assurance level (10-6). The tests to validate the shelf life of the device through the proposed shelf life were conducted using the accelerated aging method in accordance to ASTM F1980 and the test results validated 5 years shelf life.

The AXA Abutment, Multi-unit Abutment and Abutment Screw are supplied in non-sterile state. Sterilization validating testing for steam sterilization by the user has been performed in accordance with ISO 17665-1 and ISO 17665-2 to verify the sterility assurance level (10^{-6}). Validation Testing was conducted on a worst-case test article from our previously cleared device, K220562.

Modified Surface Treatment

The surface treatment evaluation has been performed in accordance with 'Section 11 of Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments – Guidance for Industry and FDA Staff".

The ZYGOMA IMPLANT has same surface and manufacturing process with the previously our cleared devices of BLUEDIAMOND IMPLANT (K241972) for the surface treatment of S.L.A.

The AXA Abutment, Multi-unit Abutment and Abutment Screw have the same anodized surface treatment and manufacturing process as our previously cleared device, MiNi Internal Implant System (K150537), AnyOne External Implant System (K203554) and BLUEDIAMOND IMPLANT System (K182448).

Performance test

Mechanical performance testing was conducted to evaluate the subject devices in accordance with the Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments.

Fatigue testing was performed using a deviated ISO 14801 test method(only potting the threaded apical end with no supporting alveolar bone) to reflect the intended clinical use of the ZYGOMA IMPLANT under an extramaxillary approach in use to ZAGA Class 4 only. All test results met the pre-established acceptance criteria, supporting substantial equivalence to the predicate devices.

MR Compatibility

The MR compatibility in additional simulation was performed to assess the risk of exposing patients who have implantable medical devices according to FDA's guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment" and applicable ASTM standards (ASTM F2052-21, ASTM F2213-17, ASTM F2119-07, ASTM F2182-19e2).

Based on the MR testing, the subject devices are classified as MR Conditional. Patients implanted with the subject devices may be safely scanned under the specific MR conditions established and consistent with those of the predicate devices, confirming substantial equivalence with respect to MR safety.

9. Summary of Clinical Data

Clinical evidence supporting the safety and effectiveness of the Subject Device (MegaGen ZYGOMA Implant System) was derived from six clinical studies involving patients with severely atrophic maxillae, maxillary defects, and other complex maxillofacial conditions requiring implant-supported rehabilitation.

Across the six studies, approximately 250 patients received a total of 677 zygomatic implants, with follow-up periods ranging from several months to more than 7.5 years. The study populations included patients with severe maxillary resorption, edentulous maxillae, maxillary defects, and complex reconstructive conditions requiring zygomatic implant-supported rehabilitation.

The reviewed studies consistently demonstrated successful implant placement, restoration of oral function, and predictable prosthetic rehabilitation. Implant survival rates ranged from approximately 93% to 100%, with most studies reporting survival rates near or above 98%, supporting the long-term effectiveness of zygomatic implant treatment. Reported adverse events were infrequent and consistent with the known risks associated with zygomatic implant surgery. Observed complications included soft tissue recession, sinus-related findings, mucositis, cutaneous fistula, peri-implantitis, oroantral communication, temporary paresthesia, and a limited number of implant failures. These events were generally manageable through routine clinical intervention, and no previously unrecognized safety concerns or unexpected device-related adverse events were identified.

Overall, the clinical evidence demonstrates that zygomatic implant systems provide a safe and effective treatment option for rehabilitation of severely compromised maxillary anatomy and supports the substantial equivalence of the Subject Device to the predicate devices.

10. Conclusions

Based on the information provided in this premarket notification, We, MegaGen Implant Co., Ltd. conclude that the subject device is substantially equivalent to the predicate and reference devices.