



October 11, 2023

MegaGen Implant Co., Ltd.
Hyejin Jung
Senior Research Engineer
45, Secheon-ro
Daegu, Dasa-eup, Dalseong-gun 42921
REPUBLIC OF KOREA

Re: K230618

Trade/Device Name: MegaGen Dental Implant Systems Portfolio - MR Conditional
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: September 6, 2023
Received: September 6, 2023

Dear Hyejin Jung:

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.

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

510(k) Number (if known)

K230618

Device Name

MegaGen Dental Implant Systems Portfolio - MR Conditional

Indications for Use (Describe)

-Healing Abutment, Cover Screw (previously cleared per K210826)

MegaGen Prosthetics are intended for use as an aid in prosthetic rehabilitation.

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)

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Indications for Use

510(k) Number (if known)

K230618

Device Name

MegaGen Dental Implant Systems Portfolio - MR Conditional

Indications for Use (Describe)

-Multi-unit Abutment, Multi-unit Angled Abutment (previously cleared per K203808)

The Multi-unit Abutment, Multi-unit Angled Abutment is intended to be surgically placed in the maxillary or mandibular arches for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

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Indications for Use

510(k) Number (if known)

K230618

Device Name

MegaGen Dental Implant Systems Portfolio - MR Conditional

Indications for Use (Describe)

-AnyOne External Implant System (previously cleared per K203554)

The AnyOne External 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 6.0 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.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

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Indications for Use

510(k) Number (if known)

K230618

Device Name

MegaGen Dental Implant Systems Portfolio - MR Conditional

Indications for Use (Describe)

-AnyOne Onestage Implant System (previously cleared per K210161)

The AnyOne Onestage 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.

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)

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Indications for Use

510(k) Number (if known)

K230618

Device Name

MegaGen Dental Implant Systems Portfolio - MR Conditional

Indications for Use (Describe)

-Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment (previously cleared per K192614)

Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment is intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. Intended for fully edentulous jaw retaining a tissue supported overdenture.

The abutments in combination with endosseous implants are used as the foundation for anchoring tooth replacements in either jaw. The attachments are used in fixed overdenture restorations that can be attached with a snap-in system.

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)

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Indications for Use

510(k) Number (if known)

K230618

Device Name

MegaGen Dental Implant Systems Portfolio - MR Conditional

Indications for Use (Describe)

-ST Internal Implant System (previously cleared per K192347)

The ST Internal Implant System is intended to be surgically placed in the maxillary or mandibular arches 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 6.0 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.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

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Indications for Use

510(k) Number (if known)
K230618

Device Name
MegaGen Dental Implant Systems Portfolio - MR Conditional

Indications for Use (Describe)
-AnyRidge Octa 1 Implant System (previously cleared per K182448)

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.

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)

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Indications for Use

510(k) Number (if known)
K230618

Device Name
MegaGen Dental Implant Systems Portfolio - MR Conditional

Indications for Use (Describe)

- Advanced Intermezzo Implant System (previously cleared per K191127)

Advanced Intermezzo Implant Systems is threaded one-piece implants designed for orthodontic onestage surgical procedures in upper and lower jaw to provide a means of prosthetic attachment to restore a patient's chewing function. Advanced Intermezzo Implant System consists of single-stage, root-form dental implants. The system is designed to provide immediate provisional implant to provide temporary support for prosthetic devices during the healing phase of permanent root form implants. Depends on a patient's quality of bone condition, Advanced Intermezzo Fixtures are to be removed within six to ten weeks after the surgery. The system is intended for immediate placement in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement retained, screw retained, or overdenture restorations.

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)

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Indications for Use

510(k) Number (if known)

K230618

Device Name

MegaGen Dental Implant Systems Portfolio - MR Conditional

Indications for Use (Describe)

-MiNi Internal Implant System (previously cleared per K150537)

The MiNi Internal Implant System is intended for two-stage surgical procedures in the following situations and with the following clinical protocols:

- The intended use for the 3.0 mm diameter MiNi implant is limited to the replacement of maxillary lateral incisors and mandibular incisors.
- Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge.
- It is intended for delayed loading.

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)

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Indications for Use

510(k) Number (if known)

K230618

Device Name

MegaGen Dental Implant Systems Portfolio - MR Conditional

Indications for Use (Describe)

-XPEED ANYRIDGE INTERNAL IMPLANT SYSYEM (previously cleared per K140091)

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.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

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Indications for Use

510(k) Number (if known)

K230618

Device Name

MegaGen Dental Implant Systems Portfolio - MR Conditional

Indications for Use (Describe)

-ANYONE™ INTERNAL IMPLANT SYSTEM (previously cleared per K123988)

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.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

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Indications for Use

510(k) Number (if known)

K230618

Device Name

MegaGen Dental Implant Systems Portfolio - MR Conditional

Indications for Use (Describe)

-XPEED ANYRIDGE INTERNAL IMPLANT SYSTEM (previously cleared per K123870)

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 Ø6.0mm) 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.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

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