Eclectic Co., Ltd.
% April Lee
Consultant
Withus Group Inc
106 Superior
Irvine, California 92620

October 18, 2024

Re: K240725
Trade/Device Name: PreXolid CAD/CAM abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: March 15, 2024
Received: September 19, 2024

Dear April 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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240725

Device Name
PreXolid CAD/CAM abutments

Indications for Use *(Describe)*
PreXolid CAD/CAM Abutments are intended for use on endosseous dental implants in the edentulous or partially edentulous maxilla or mandible, as an aid in the prosthetic rehabilitation.

Compatible Implant System	Implant Body Diameter, mm	Implant Platform Diameter, mm
XPEED AnyRidge Internal Implant System, Standard Type	5.0, 5.5	3.3
XPEED AnyRidge Internal Implant System, Standard Type	5.0, 5.5, 6.0	4.0
XPEED AnyRidge Internal Implant System, Standard Type	6.0, 6.5, 7.0, 7.5, 8.0	4.8

For PreXolid CAD/CAM Abutments, all digitally designed abutments for use with PreXolid CAD/CAM Abutments are intended to be sent to an Eclectic-validated milling center for manufacture.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitter
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Email: withus6664@gmail.com
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Device Information

- Trade Name: PreXolid CAD/CAM abutments
- Common Name: Dental Abutment System
- Classification Name: Endosseous dental implant abutment
- Product Code: NHA
- Panel: Dental
- Regulation Number: 872.3630
- Device Class: Class II
- Date prepared: 10/15/2024

Predicate Devices:

Primary Predicate

- K220562, TiGEN Abutment, ZrGEN Abutment and Scan Healing Abutment by Megagen implant Co., Ltd.

Reference Device

- K122231, XPEED ANY RIDGE INTERNAL IMPLANT SYSTEM by MEGAGEN Implant Co., Ltd.

Indication for Use:

PreXolid CAD/CAM Abutments are intended for use on endosseous dental implants in the edentulous or partially edentulous maxilla or mandible, as an aid in the prosthetic rehabilitation.

Compatible Implant System	Implant Body Diameter, mm	Implant Platform Diameter, mm
XPEED AnyRidge Internal Implant System, Standard Type	5.0, 5.5	3.3
XPEED AnyRidge Internal Implant System, Standard Type	5.0, 5.5, 6.0	4.0
XPEED AnyRidge Internal Implant System, Standard Type	6.0, 6.5, 7.0, 7.5, 8.0	4.8

For PreXolid CAD/CAM Abutments, all digitally designed abutments for use with PreXolid CAD/CAM Abutments are intended to be sent to an Eclectic-validated milling center for manufacture.

Device Description:

The subject patient-specific abutment, *PreXolid CAD/CAM Abutments* is an abutment used in fabricating fully patient-specific abutments made of Ti-6Al-4V ELI, conforming to ASTM Standard F136. Each patient-specific abutment is individually prescribed by the clinician.

The subject devices are available in diameters ranging from 5.0mm to 8.0mm. The subject device is provided with an abutment screw.

PreXolid CAD/CAM Abutments are compatible with XPEED AnyRidge Internal Implant System (K122231).

Proprietary Name	XPEED AnyRidge Internal Implant System
Compatible Implants (K number)	K122231
Type/Implant Interface connection	Standard Type/Internal Hex 2.3
Implant Body Diameter size(mm)	5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0
Implant Platform Diameter(mm)	3.3, 4.0, 4.8

The allowable ranges of design parameters after CAD/CAM patient-matching are as follows:

Minimum wall thickness(mm)	0.45
Maximum angulation(°)	25
Minimum gingival collar height(mm)	2.00
Maximum gingival collar height(mm)	5.00
Minimum gingival collar(ø)	4.00
Maximum gingival collar(ø)	9.50 , 11.50
Minimum post height (mm)	4.00
Maximum post height (mm)	6.00

*The abutment post height is considered by FDA to be the “stump” portion above the gingival collar, to which the restorations attach.

The subject abutments are provided non-sterile and are intended to be sterilized by the clinician.

Materials:

- Pre-milled abutments and screws are fabricated from Ti-6Al-4V ELI, conforming to ASTM Standard F136.

Summaries of Technology Characteristics The subject device is substantially equivalent to the current cleared device, K220562. They are substantially equivalent in intended use, material and identical connection interfaces across all individual diameters and connection types.

Detailed comparison demonstrating substantial equivalence is provided below:

<table>
<tr><th></th><th>Subject Device</th><th>Primary Predicate Device</th></tr>
<tr><td>510(k) Number</td><td>K240725</td><td>K220562</td></tr>
<tr><td>Device Name</td><td>PreXolid CADCAM Abutments</td><td>TiGen Abutment</td></tr>
<tr><td>Manufacturer</td><td>Eclectic Co., Ltd.</td><td>MegaGen Co., Ltd.</td></tr>
<tr><td>Indications for Use</td><td>PreXolid CAD/CAM Abutments are intended for use on endosseous dental implants in the edentulous or partially edentulous maxilla or mandible, as an aid in the prosthetic rehabilitation.

<table>
<tr><th>Compatible Implant System</th><th>Implant Body Diameter, mm</th><th>Implant Platform Diameter, mm</th></tr>
<tr><td>XPEED AnyRidge Internal Implant System, Standard Type</td><td>5.0, 5.5</td><td>3.3</td></tr>
<tr><td>XPEED AnyRidge Internal Implant System, Standard Type</td><td>5.0, 5.5, 6.0</td><td>4.0</td></tr>
<tr><td>XPEED AnyRidge Internal Implant System, Standard Type</td><td>6.0, 6.5, 7.0, 7.5, 8.0</td><td>4.8</td></tr>
</table>
For PreXolid CAD/CAM Abutments, all digitally designed abutments for use with PreXolid CAD/CAM Abutments are intended to be sent to an Eclectic-validated milling center for manufacture.</td><td>The TiGEN Abutment, ZrGEN Abutment and Scan Healing Abutment are intended for use on endosseous dental implants in the edentulous or partially edentulous maxilla or mandible, as an aid in prosthetic rehabilitation.

For TiGEN Abutment and ZrGEN Abutment, all digitally designed abutments for use with TiGEN Abutment and ZrGEN Abutment are intended to be sent to a MegaGen-validated milling center for manufacture.</td></tr>
<tr><td>Abutment Design</td><td>CAD/CAM Blank</td><td>CAD/CAM Blank</td></tr>
<tr><td>Restoration</td><td>Single-unit & Multi-unit</td><td>Single-unit & Multi-unit</td></tr>
<tr><td>Abutment Angle</td><td>Up to 25°</td><td>Up to 30°</td></tr>
<tr><td>Abutment/Implant Interface</td><td>Internal</td><td>Internal, External</td></tr>
<tr><td>Abutment Material</td><td>Ti-6AI-4V-ELI</td><td>Ti-6AI-4V-ELI</td></tr>
</table>

<table>
<tr><td>Sterilization</td><td>Non-sterile
User sterilization</td><td>Non-sterile;
Intended for terminal sterilization via autoclave</td></tr>
<tr><td>Pre-milled Abutment Diameter(mm)</td><td>10, 14</td><td>10, 12</td></tr>
<tr><td>Implant Body Diameter(mm)</td><td><table><tr><td colspan="2">Standard Type</td></tr><tr><td>XPEED AnyRidge Internal Implant System</td><td>5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0</td></tr></table></td><td><table><tr><td colspan="2">Standard Type</td></tr><tr><td>XPEED AnyRidge Internal Implant System</td><td>3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0</td></tr><tr><td>AnyOne Internal Implant System</td><td>3.5, 4.0, 4.5, 5.0, 6.0, 7.0, 7.5, 8.0</td></tr><tr><td>MiNi Internal Implant System</td><td>3.0, 3.25</td></tr><tr><td>AnyRidge Octa 1 Implant System</td><td>3.6, 3.7, 4.0, 4.1, 4.4, 4.8, 5.0, 5.5</td></tr><tr><td colspan="2">Octa Level Type</td></tr><tr><td>XPEED AnyRidge Internal Implant System</td><td>3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 7.0, 7.5, 8.0</td></tr><tr><td>AnyOne Interanl Implant System</td><td>3.5, 4.0, 4.5, 5.0, 6.0, 7.0, 7.5, 8.0</td></tr><tr><td>AnyRidge Octa 1 Implant System</td><td>3.6, 3.7, 4.0, 4.1, 4.4, 4.8, 5.0, 5.5</td></tr></table></td></tr>
</table>

Substantial Equivalence Discussion

1. Similarities
The subject device has the same characteristic for the followings compared to the predicate device, K220562.
- Indications for use, abutment design, restoration, implant interface and abutment material, and the sterilization method.

2. Differences
The subject device does not include an octa abutment interface and has a different pre-milled abutment diameter, the variations in compatible implant body sizes, implant platform size, and maximum abutment angle. Despite these differences, the fixtures compatible with the subject device, as well as the limitations on patient-specific abutments, including the maximum angle, fall within the range of those for the predicate device.

3. Discussion
The subject device and primary predicate device are cylindrical titanium abutments with precision implant/abutment interface for use in fabricating a patient-specific abutment at a manufacturer-validated milling center.
The subject device and predicate device have similar Indications for use, Abutment design, Restoration, Abutment/implant interface, and Abutment material. These similarities effectively demonstrate the substantial equivalence between the two devices.

For the abutment angle of subject devices, the worst case was selected for XPEED AnyRidge Internal Implant System, standard type and fatigue test was performed to confirm the substantial equivalence in accordance with ‘ISO 14801’ and “Class II Special Controls Guidance Document: Root form Endosseous

Dental Implants and Endosseous Dental implant Abutment". The test result supports that the subject device is substantially equivalent to the predicate device and the difference is not affecting the substantial equivalence. The subject device and predicate device(K220562), have common as following: Internal Interface. The subject device is supplied in non-sterile state. Sterilization validating testing for steam sterilization by the user has been performed in accordance with ISO 11137 and ISO 17665-1, 2 to verify the sterility assurance level (10-6).

Based on the information provided, it is concluded that the subject device is substantially equivalent to the predicate device.

Non-Clinical Testing

The subject device was tested to evaluate its substantial equivalence according to the following standards:

- Fatigue Tests on the subject device were conducted under the worst-case scenario according to ISO 14801:2016
- Biocompatibility testing according to ISO 10993-1:2009
- End User Sterilization Validation Test Report according to ANSI/AAMI ST79, ISO 17665-1, ISO 17665-2, ISO 11737-1, ISO 11737-2, and ISO 11138-1
- Reverse engineering analysis of OEM implant bodies, OEM abutments, and OEM abutment screws to confirm compatibility.

The results of the aforementioned tests have successfully met the criteria outlined in the standards, affirming the device's suitability for use.

Biocompatibility Testing was performed according to ISO 10993-1:2009, "*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process,*" and to the FDA Guidance document, "*Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process', Guidance for Industry and Food and Drug Administration Staff"*, Document issued on: June 16, 2016", for subject abutments.

Non-clinical test data was conducted in accordance with FDA Guidance "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments". This testing involved examining finished assembled implant/abutment systems of the worst-case scenario (smallest diameter with maximum angulation) through fatigue testing.

The recommended end user sterilization has been validated according to ISO 17665-1 and ISO 17665-2 and to applicable recommendations in the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, issued on March 17, 2015" for subject abutments.

Dimensional analysis and reverse engineering of the implant-to-abutment connection platform were conducted, encompassing an assessment of maximum and minimum dimensions of critical design aspects, tolerances, and cross-sectional images of the submission device and compatible implant body, as well as the OEM implant abutment and implant body. The testing confirmed implant to abutment compatibility and established substantial equivalency of the proposed device with predicate devices.

MR Environment Condition

Non-clinical worst-case MRI review was performed to evaluate the metallic device 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, dental 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.
The results of the above non-clinical tests have met the criteria of the standards and demonstrated the substantial equivalence with the predicate device.
Clinical testing was deemed unnecessary to establish substantial equivalency of the device.

Conclusion

PreXolid CAD/CAM Abutments constitutes a substantially equivalent medical device, meeting all the declared requirements of its intended use. This system has similar intended use and fundamental scientific technology as its predicate devices. Therefore, PreXolid CAD/CAM Abutments and their predicates are substantially equivalent.