



June 12, 2025

DMAX Co., Ltd.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
18881 Von Karman STE 160
Irvine, California 92612

Re: K250826
Trade/Device Name: Multi M Series
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH,
Dated: February 20, 2025
Received: March 18, 2025

Dear Priscilla Chung:

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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
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.

K250826

?

Please provide the device trade name(s).

?

Multi M Series

Please provide your Indications for Use below.

?

The Multi M Series is used in the manufacture of dental prosthesis.

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 K250826

This summary of 510(K) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 3/13/2025

1. Submitter

DMAX Co., Ltd.
89, Hosan-ro, Dalseo-gu, Daegu, 42710, Korea
Tel: 82-53-592-3146

2. U.S Agent/Contact Person

Priscilla Chung
LK Consulting Group USA, Inc.
18881 Von Karman Ave STE 160, Irvine CA 92612
Phone: 714.202.5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device

- Trade Name: Multi M Series
- Common Name: Dental Frame Material for Dental Prosthesis
- Classification Name: Porcelain Powder for Clinical Use
- Product Code: EIH
- Classification regulation: 21 CFR 872.6660

4. Predicate Device:

Zmaxx T series by DMAX Co., Ltd. (K161219)

5. Description:

Multi M Series is zirconia-based ceramic provided in various shapes such as round and it is used to manufacture cores of all ceramic crowns and is classified into ISO 6872 Type 2 Class 5. It is used to manufacture ceramic restorations through cutting process by dental MAD/MAM, computer-assisted design system, or CAD/CAM system. The subject device offers 278 different shades to meet the needs of different patients' tooth colors. It also offers various shape types to be used with various jigs for CAD/CAM milling machine. Multi M Series offers various types as follows: W-type, Z-type. These different types are to accommodate the different types of the jig that is built-in CAD/CAM machine. Users can

choose a type which fits the jig they have.

6. Indication for use:

The Multi M Series is used in the manufacture of dental prosthesis.

7. Basis for Substantial Equivalence

7.1. Comparison Chart

	Subject device	Predicate device
Device Name	Multi M series	Zmaxx T series
510(k)	-	K161219
Product Code	EIH	EIH
Manufacturer	DMAX Co., Ltd.	DMAX Co., Ltd.
Technology	-	-
Indication for Use	Multi M Series is used in the manufacture of dental prosthetics.	Zmaxx T Series is used in the manufacture of dental prosthetics.
Principles of Operation	Install the block on milling machine, upload a designed file and process it.	Install the block on milling machine, upload a designed file and process it.
Mechanical Testing	ISO 6872:2015	ISO 6872:2008
Prescription Use	Prescription only	Prescription only
Target population	General, mostly adults	General, mostly adults
Type of Packaging	Paper box container	Paper box container
Packaging Volume(EA)	1EA	1EA
Shade	278 shades based on Vita shade guide	3 colors (A0, A0.5, A2)
Storage Conditions	5-50 °C	10~35°C
General Physical Form	Solid	Solid
Sterility	Non-Sterile	Non-Sterile
CTE(coefficient of thermal expansion)	$(10.6\pm 0.5)\times 10^{-6}K^{-1}$ (meeting the ISO 6872 requirement)	$(10.6\pm 0.5)\times 10^{-6}K^{-1}$ (meeting the ISO 6872 requirement)
Flexural Strength	>800MPa (meeting the ISO 6872 requirement)	>600MPa (meeting the ISO 6872 requirement)
Chemical solubility	<100 ug/cm ² (meeting the ISO 6872 requirement)	<2000 ug/cm ² (meeting the ISO 6872 requirement)
Material component	ZrO ₂ , HfO ₂ , Y ₂ O ₃ , Al ₂ O ₃ , SiO ₂ , Fe ₂ O ₃ , Er ₂ O ₃ , CaO	ZrO ₂ , HfO ₂ , Y ₂ O ₃ , Al ₂ O ₃ , SiO ₂ , Fe ₂ O ₃ , Er ₂ O ₃
Biocompatibility	Non-toxic and biocompatible (Meeting the ISO 10993-5, 10 and 10993-11 requirements)	Non-toxic and biocompatible (Meeting the ISO 10993-5, 10 and 10993-11 requirements)

7.2. Substantial Equivalence

The Multi M series is substantially equivalent to the Zmaxx T series (K161219) made by our company. Although the 510k applicant is Maxx Digm, Inc., we are a contract manufacturer of the device.

The following comparison table is presented to demonstrate substantial equivalence. They share similar materials and similar physical / chemical properties. However, the mixing ratios of the raw materials are different between the devices. Despite these differences, the performance test results per ISO 6872 show that the subject device is substantially equivalent to the predicate devices in physical and chemical properties and meets the necessary requirements. Based on the comparison between the two devices and the performance testing results presented in this 510K, we conclude that the subject device is substantially equivalent to the predicate devices.

8. Non-Clinical Testing

- Performance Tests including Appearance, Dimensions, Packaging, Uniformity (ISO 6872), Extraneous Materials (ISO 6872), Flexural Strength (ISO 6872), Linear thermal Expansion Coefficient (ISO 6872), Chemical Solubility (ISO 6872), Monoclinic Phase Fraction (ISO 13356), Radioactivity (ISO 6872), Flexural strength after accelerated aging (ISO 13356)
- Biocompatibility tests in accordance with ISO 10993-3, 5, 6, 10, 11, and 33

9. Conclusion

The subject device and the predicate device have the same intended use and have the same technological characteristics. Based on the similarities and the test results, we conclude that the subject device is substantially equivalent to the predicate device.