DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Maxx Digm, Inc.
Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
800 Roosevelt Ste 417
Irvine, California 92620

January 26, 2017

Re: K161219
Trade/Device Name: Zmaxx T Series
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: April 28, 2016
Received: April 29, 2016

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner DDS, MA

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name

Zmaxx T Series

Indications for Use *(Describe)*

Zmaxx T Series is used in the manufacture of dental prosthetics.

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

(K161219)

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

Date: ___December 27, 2016___

1. Applicant / Submitter:

Maxx Digm, Inc.

3265 Kifer Road
Santa Clara, CA 95051

Tel: 408-462-9608
Fax: 408-542-9871

2. Submission Correspondent:

Priscilla Chung
LK Consulting Group USA, Inc.
800 Roosevelt Ste 417,
Irvine CA 92620
Phone: 714-202-5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device:

Proprietary Name:	Zmaxx T Series
Common Name:	Dental Frame Material for Dental Prosthesis
Classification Name:	Porcelain Powder for Clinical Use
Classification:	Class II, 21 CFR 872.6660
Classification Product Code:	EIH

4. Predicate Device:

Primary Predicate Device: NATURAZ SERIES (K091096) by The Dental Solutions, Inc.
Reference Predicate Device: BruxZir™ Anterior (K143330) by Prismatik Dentalcraft, Inc.

5. Device Description:

Zmaxx T Series is zirconia-based ceramic provided in various shapes such as round and square and it is used to manufacture cores of all ceramic crowns, and is classified into ISO 6872 Type 2 Class 4. 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 three 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.

Zmaxx T Series offers various types as follows: W-type, T-type, D-type, Z-type, A-type, C-type, B-type, K-type, and Q-type. These different types are to accommodate the different types of the jig that is built-in CAD/CAM machine. User can choose a type which fits the jig they have.

Type	Size Range	Weight Range
W-type	98.5mm(D) x 10-25mm(T)	250-580g
T-type	100mm(D) x 10-25mm(T)	250-615g
D-type	98mm(D) x 10-25mm(T)	250-595g
Z-type	95mm(D) x 10-30mm(T)	230-700g
A-type	90mm(W)×73mm(L)×12-25mm(H)	210-420g
C-type	15.5-22mm(W)×19-25(L)×20-65(H)	20-125g
B-type	65(W)×35(L)×12-22mm(H)	85-155g
K-type	75(W)×45(L)×12-22mm(H)	127-260g
Q-type	100(W)×100(L)×12-22mm(H)	380-665g

6. Indications for Use:

Zmaxx T Series is used in the manufacture of dental prosthetics.

7. Performance Data(Non-Clinical):

The following properties were tested based on the referenced standards. All the test results support substantial equivalence to the predicate devices.

- ISO 6872 - Freedom of Extraneous Materials , Radiation Emission , Flexural Strength,
- Thermal Expansion Coefficient, Chemical Solubility, Density, Shrinkage Factor
- ISO 13356 - Mono Clinic Phrase Rate
- ISO 10993-5 - Cytotoxicity
- ISO 10993-10 - Sensitization & Irritation
- ISO 10993-11 - Acute Systemic Toxicity
- Other bench testing - Visual Inspection, Dimension Accuracy, Package, Uniformity

8. Substantial Equivalence

The Zmaxx T Series is substantially equivalent to the NATURAZ SERIES (K091096) by The Dental Solutions, Inc. and BruxZir™ Anterior (K143330) by Prismatik Dentalcraft, Inc.
The following comparison table is presented to demonstrate substantial equivalence. They share the similar

material 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 shows that the subject device is substantially equivalent to the predicate devices in physical and chemical properties and meets the necessary requirements. In addition, the subject device has been tested for cytotoxicity (ISO 10993-5), sensitization (ISO 10993-10), irritation (ISO 10993-10), and acute systemic toxicity (ISO 10993-11) to meet the biocompatibility requirements.

Based on the comparison between the two devices and the performance testing results presented in this 510K, we conclude that the Zmaxx T Series is substantially equivalent to the predicate devices.

	Subject Device	**Primary Predicate Device**	**Reference Predicate Deice**
510(k) Number	K161219	K091096	K143330
Device Name	Zmaxx T Series	NATURAZ SERIES	BruxZir™ Anterior
Common Name	Porcelain, Powder for clinical use	Porcelain, Powder for clinical use	Porcelain, Powder for clinical use
510k Applicant	Maxx Digm, Inc.	The Dental Solutions, Inc.	Prismatik Dentalcraft, Inc.
Contract Manufacturer	DMAX Co. Ltd.	DMAX Co., Ltd.	-
Indication For Use	Zmaxx T Series is used in the manufacture of dental prosthetics. DMAX CO., LTD proposes that the materials distributed within the United States be labeled	NaturaZ Series is used in the manufacture of dental prosthetics. The Dental Solution, Inc. proposes that the materials distributed within the United States be labeled: "Caution: Federal (US) law restricts the sale of the device to, or on the order of, licensed professionals."	The device is indicated for use by dental technicians in the construction of custom made all ceramic restorations for anterior and posterior location.
CTE(coefficient of thermal expansion	$(10.6\pm0.5)\times10^{-6}K^{-1}$ (meeting the ISO 6872 requirement)	$(11.5\pm0.5)\times10^{-6}K^{-1}$ (meeting the ISO 6872 requirement)	$11\times10^{-6}K^{-1}$ (meeting the ISO 6872 requirement)
Flexural strength	>600MPa (meeting the ISO 6872 requirement)	>800MPa (meeting the ISO 6872 requirement)	>650MPa (meeting the ISO 6872 requirement)
Chemical solubility	<2000 ㎍/㎠ (meeting the ISO 6872 requirement)	<100 ㎍/㎠ (meeting the ISO 6872 requirement)	<2000 ㎍/㎠ (meeting the ISO 6872 requirement)
Material Component	ZrO_2, HfO_2, Y_2O_3, Al_2O_3, SiO_2, Fe_2O_3, Er_2O_3	ZrO_2, HfO_2, Y_2O_3, Al_2O_3, SiO_2, Fe_2O_3	ZrO_2, HfO_2, Y_2O_3, Al_2O_3, SiO_2, Fe_2O_3, Er_2O_3
Shade	A0, A0.5, A2	A0	5 shades
Principle 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.	Install the block on milling machine, upload a designed file and process it

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)	Non-toxic and biocompatible (Meeting the ISO 10993-3, 5,10 and10993-11 requirements)

9. Conclusion:

Based on the testing results, Maxx Digm, Inc. concludes that the Zmaxx T Series are substantially equivalent to the predicate device.