



DMAX Co, Ltd.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
690 Roosevelt
Irvine, California 92620

March 8, 2018

Re: K173769

Trade/Device Name: DMAX Coloring Liquid; Chang's Liquid; Confident Coloring Liquid; CAMEleon Coloring Liquid

Regulation Number: 21 CFR 872.6660

Regulation Name: Porcelain Powder for Clinical Use

Regulatory Class: Class II

Product Code: EIH

Dated: November 30, 2017

Received: December 11, 2017

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

For 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

Indications for Use

510(k) Number (if known)

K173769

Device Name

DMAX coloring liquid, Chang's liquid, Confident coloring liquid, and CAMEleon coloring liquid

Indications for Use (Describe)

DMAX coloring liquid, Chang's liquid, Confident coloring liquid, and CAMEleon coloring liquid can be used as an accessory to zirconium dioxide dental restorative material to provide individual tooth (or teeth) shading. It is intended to be used solely by certified dental technicians for fabrication of zirconium dioxide restorations for individual dental patients.

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.

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510(k) Summary

Date: Mar 07, 2018

1. Applicant / Submitter:

DMAX CO., LTD.

37-26, Dasa-ro 71-gil, Dasa-eup,
Dalseong-gun, Daegu, 42907, Republic of Korea

Contact Person: Hyeon Seok Cho

2. Submission Correspondent:

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

3. Device:

Proprietary Name:	DMAX Coloring Liquid Chang's Liquid Confident Coloring Liquid CAMEleon Coloring Liquid
Common Name:	Liquid Stain for Dental Zirconium Prosthesis
Classification Name:	Porcelain Powder for Clinical Use
Classification:	Class II, 21 CFR 872.6660
Classification Product Code:	EIH

4. Predicate Device:

LUMINESSE® PRE-SINTERED ZIRCONIA COLORING LIQUID (K143090)
by Talladium, Inc.

5. **Device Description:**

The subject device is water-based solution. It is used for the individual staining of dental zirconia frameworks and restorations prior to the final sintering. It enables trained dental technicians to adjust the restoration to match the natural color of the patient's teeth.

The liquid has 45 shades. 45 shades are available in 15ml, 20ml, 30ml, 40ml and 100ml volumes. We offer the product in four different names: DMAX Coloring Liquid, Chang's Liquid, Confident Coloring Liquid, CAMEleon Coloring Liquid. They are just different names for the same products.

- DMAX Coloring Liquid is available in 20ml, 30ml, and 100ml volumes in 45 shades.
- Chang's Liquid is available in 15ml and 40ml volumes in 45 shades.
- Confident Coloring Liquid is available in 30ml volume in 45 shades.
- CAMEleon Coloring Liquid is available in 20ml, 100ml volumes in 45 shades.

6. **Indications for Use:**

DMAX coloring liquid, Chang's liquid, Confident coloring liquid, and CAMEleon coloring liquid can be used as an accessory to zirconium dioxide dental restorative material to provide individual tooth (or teeth) shading. It is intended to be used solely by certified dental technicians for fabrication of zirconium dioxide restorations for individual dental patients.

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.

- Shelf Life Test
- ISO 10993-5 - Cytotoxicity
- ISO 10993-10 - Sensitization & Irritation
- ISO 10993-11 - Oral mucosa irritation
- Other bench testing - Appearance, Volume, Packaging, Uniformity, Impurity, Chemical Solubility

8. Substantial Equivalence

The subject device is compared to the predicate device, LUMINESSE® PRE-SINTERED ZIRCONIA COLORING LIQUID (K143090), in the table below.

	Subject device	Predicate device
Device Name	DMAX coloring liquid Chang's liquid Confident coloring liquid CAMEleon coloring liquid	LUMINESSE® PRE-SINTERED ZIRCONIA COLORING LIQUID
510(k)	K173769	K143090
Product Code	EIH	EIH
Manufacturer	DMAX Co., Ltd.	Talladium, Inc.
Technology	Water-based with inorganic pigments	Water-based with inorganic pigments
Indication for Use	DMAX coloring liquid, Chang's liquid, Confident coloring liquid, and CAMEleon coloring liquid can be used as an accessory to zirconium dioxide dental restorative material to provide individual tooth (or teeth) shading. It is intended to be used solely by certified dental technicians for fabrication of zirconium dioxide restorations for individual dental patients.	Luminesse Pre-Sintered Zirconia Coloring Liquid is a device that can be used as an accessory to zirconium dioxide dental restorative material such as Luminesse ZR blanks to provide individualized tooth (or teeth) shading. It is intended to be used solely by certified dental technicians for fabrication of all ceramic restorations for individual dental patients.
Principles of Operation	Brush or immerse zirconia ceramic with coloring liquid before sintering	Brush or immerse zirconia ceramic with coloring liquid before sintering
Prescription Use	Prescription only	Prescription only
Target population	General, mostly adults	General, mostly adults
Type of Packaging	Liquid container	Liquid container
Packaging Volume(ml)	15,20,30,40,100	100 and 250
Shade	45 colors	16 colors
Storage Conditions	1 year at 2-28 °C	3-4 years at 4-10 °C
General Physical Form	Liquid	Liquid
Sterility	Non-Sterile	Non-Sterile
pH	5.5~8.0	6.5-7.2
Boiling Point	100°C	100°C
Density	1.00~1.10 g/cm ³	1.05-1.10 g/cm ³
Specific Gravity	1.00~1.10	1.05-1.10
Solubility in Water	100%	100%
Color	45 shades	VITA® - 16 shades
Odor	Characteristic odor	Characteristic odor

The subject device is the same as the predicate device in the indications for use, principle of operation, and device characteristics. Both devices are water-based with inorganic pigments and employs brushing or immersing method for use.

The differences between the subject device and the predicate device are packaging volume and the number of shades offered. Another difference is shelf life and storage conditions; however, the shelf life test results of the subject device support that the subject device is substantially equivalent to the predicate device.

9. Conclusion:

Based on the testing results, DMAX CO., LTD. concludes that the subject device is substantially equivalent to the predicate device.