



June 30, 2023

Doctus Global  
% Bokyeong Kim  
Senior Researcher  
GMS Consulting  
4th Floor, Digital Cube, 34, Sangamsan-ro  
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SOUTH KOREA

Re: K231264  
Trade/Device Name: Easy On Universal Glaze & Stain  
Regulation Number: 21 CFR 872.6660  
Regulation Name: Porcelain Powder For Clinical Use  
Regulatory Class: Class II  
Product Code: EIH  
Dated: April 28, 2023  
Received: May 2, 2023

Dear Bokyeong Kim:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 <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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
Michael E. Adjodha -S

Michael E. Adjodha, M.ChE.  
Assistant Director  
DHT1B: Division of Dental and  
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Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K231264

Device Name

Easy On Universal Glaze & Stain

Indications for Use (Describe)

Easy On Universal Glaze & Stain is suitable for the esthetic individualization of monolithic or minimally reduced dental crown and bridge constructions made of zirconium dioxide or lithium disilicate.

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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 Gyeonggi-do, Republic of Korea

## 510(k) Summary

[As Required by 21 CFR 807.92]

### 1. Date Prepared [21 CFR 807.92(a)(a)]

April 28, 2023

### 2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Sponsor: GMS Consulting
  - Address: 4th Floor, Digital Cube, 34, Sangamsan-ro, Mapo-gu, Seoul, Republic of Korea,03909
- Contact Name: Beom-jin Choi, R&D Principal Researcher
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  - Email Address: doctus2021@naver.com
- Name of Manufacturer: Doctus Global
  - Address: RN.313, 51, Samwon-ro, Deogyang-gu, Goyang-si, Gyeonggi-do, Republic of Korea

### 3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Regulation Name	Porcelain Powder for Clinical Use
Product Name	Easy On Universal Glaze & Stain
Model Name	Easy On Universal Stain
Regulation Number	872.6660
Classification Product Code	EIH
Device Class	2
510k Review Panel	Dental



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#### **4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]**

The identified predicate devices within this submission are shown as follow:

##### Predicate Device #1

- 510(k) Number: K193588
- Applicant: Dental Direkt GmbH
- Regulation Name: Porcelain Powder for Clinical Use
- Proprietary Name: DD Contrast
- Classification Product Code: EIH
- Regulation Number: 21 CFR 872.6660

The predicate device has not been subject to a design-related recall

## **5. Description of the Device [21 CFR 807.92(a)(4)]**

### **5.1. General**

Doctus Global offers two kinds of Easy On Universal Glaze & Stain:

- ✓ Easy On Universal Stain for artificial teeth
- ✓ Easy On Universal Gum Stain for dental prosthesis, artificial gum tissue portion.
- ✓ Easy Liners for Porcelain powder build-up process.
- ✓ Easy Add On for Correcting and Repair process.
- ✓ Easy On Crystal Glaze for glazing Lithium disilicate CAD/CAM block crown and bridge
- ✓ Build Up Liquid for porcelain powder build up process

Both systems and other items are a useful finishing system made of paste type Stain & Glaze for dental ceramics.

Fluorescent layering materials for staining, structuring and glazing. With Easy On Universal Stain & Gum Stain, you can easily and quickly achieve high quality dental ceramic prosthesis.

Easy On Universal Stain consists of different types of self-glazing colors with various levels of translucency, each Unique replicate natural tooth shade and gum tissue colors and structures, such as incisal translucency, mamelons, detail expressions, halos, and gum tissue.

Over paint Easy On Universal Stains we layer Easy On Universal Structures. With Easy On Universal Structure you can create tooth surface textures found in natural enamel area and gum tissues, in light and thin thicknesses of 0.1 mm - 0.3 mm. With easy applying and high stability, individual surface structures can easily be integrated into the paste with small brush. The low firing temperature does not change the details of the surface, so reliable and aesthetic results are achieved with one or two firings.

## 5.2. Device composition

\* The components of the kit below table are sold individually or in kits. {1} ~ 2}

### 1) Easy On Universal Stain Full Kit



- Composition

			
Easy On Universal Glaze	Stain-Shade A	Stain-Shade B	Stain-Shade C
			
Stain-Shade D	Stain-Light Brown	Stain-Red Brown	Stain-Dark Brown
			
Structure Stain-Enamel	Stain-White	Stain-Ivory	Stain-Pink

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Stain-Red	Stain-Orange	Stain-Light Blue	Stain-Dark Blue
			
Stain-Gray	Structure Stain-Clear	Easy On Universal Glaze Liquid	
			
Brush			

No.	Name	Description
1	Easy On Universal Glaze	A transparent glaze layer is formed on the outer surface of the ceramic Inlay, Onlay, Crown, Crown & Bridge and Zirconia dental prosthesis
2	Stain-Shade A	Among the basic shade of teeth, the stain that expresses the basic colors of the A
3	Stain-Shade B	Among the basic shade of teeth, the stain that expresses the basic colors of the B
4	Stain-Shade C	Among the basic shade of teeth, the stain that expresses the basic colors of the C
5	Stain-Shade D	Among the basic shade of teeth, the stain that expresses the basic colors of the D
6	Stain-Light Brown	Stain that expresses bright brown color on the exterior of dental prosthesis
7	Stain- Red Brown	Stain that expresses red brown color on the exterior of dental prosthesis
8	Stain- Dark Brown	Stain that expresses dark brown color on the exterior of dental



		prosthesis
9	Structure Stain-Enamel	Stain that expresses the color and transparent of the Enamel layer
10	Stain-White	Stain that expresses the lightest part of the surface of dental prosthesis
11	Stain-Ivory	Stain that expresses lighter part of the surface of dental prosthesis
12	Stain-Pink	Stain representation of gingiva and cervical part of the dental prosthesis
13	Stain-Red	Stain representation of gingiva and red color part of the dental prosthesis
14	Stain-Orange	Stain representation of occlusal and cervical part of the dental prosthesis
15	Stain-Light Blue	Stain that expresses the enamel layer of the anterior and posterior tooth
16	Stain-Dark Blue	Stain that expresses the enamel layer of the anterior and posterior tooth
17	Stain-Gray	Stain that expresses the enamel layer of the anterior and posterior tooth
18	Structure Stain-Clear	Stain for representing the most transparent layer of the overall appearance of dental prosthesis
19	Easy On Universal Glaze Liquid	If the viscosity of the product increases during use, dilute it
20	Brush	Painting instrument







2) Easy On Universal Gum Stain Full Kit



- Composition

			
Easy On Universal Glaze	Gum Stain-G1	Gum Stain-G2	Gum Stain-G3
			
Gum Stain-G4	Gum Stain-G5	Gum Stain-G6	Gum Stain-G7
			
Gum Stain-Dark Red	Gum Stain-Purple	Gum Structure Stain- GS1	Gum Structure Stain- GS2

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Gum Structure Stain-GS3	Gum Structure Stain-GS4	Gum Structure Stain-GS5	Easy On Universal Glaze Liquid
			
Brush			
			
Pallet			
No.	Name	Description	
1	Easy On Universal Glaze	A transparent glaze layer is formed on the outer surface of the ceramic Inlay, Onlay, Crown, Crown & Bridge and Zirconia dental prosthesis	
2	Gum Stain-G1	Stains for the gingiva part of the dental prosthesis. Becomes darker as it increases by 1 to 7	
3	Gum Stain-G2		
4	Gum Stain-G3		
5	Gum Stain-G4		
6	Gum Stain-G5		
7	Gum Stain-G6		
8	Gum Stain-G7		
9	Gum Stain-Dark Red	Stain for expressing the dark red color of the attached gingiva part of dental prosthesis	
10	Gum Stain-Purple	Stain for expressing the purple color of the attached gingiva part of dental prosthesis	
11	Gum Structure Stain-GS1	Stains for the gingiva part outer detail texture expression of the dental prosthesis. Becomes darker as it increases by 1 to 5	
12	Gum Structure Stain-GS2		
13	Gum Structure Stain-GS3		
14	Gum Structure Stain-GS4		
15	Gum Structure Stain-GS5		
16	Easy On Universal Glaze Liquid	If the viscosity of the product increases during use, dilute it	

17	Brush	Painting instrument
18	Pallet	Products for mixing and diluting stains



*\* The items below are sold individually only. {3} ~ 6}*

### 3) Easy Liner

		
Easy Liner Light	Easy Liner Dark	Easy Liner Pink

No.	Name	Description
1	Easy Liner Light	Materials for increasing the combined strength and shear strength of Zirconia coping and Ceramic Powder in the process of firing and completing by adding Ceramic Powder to a substructure made of bright Zirconia framework
2	Easy Liner Dark	Materials for increasing the combined strength and shear strength of Zirconia coping and Ceramic Powder in the process of firing and completing by adding Ceramic Powder to a substructure made of bright Zirconia framework
3	Easy Liner Pink	Materials for increasing the combined strength and shear strength of Zirconia coping and Ceramic Gum color Powder in the process of firing and completing by adding Ceramic Gum Powder to a substructure made of bright Zirconia framework

### 4) Easy Add On

	
Easy Add On Enamel	Easy Add On Clear



No.	Name	Description
1	Easy Add On Enamel	Materials for complete the finished dental prosthesis, that complements the appearance of the enamel translucent layer on the outer surface of the artificial tooth
2	Easy Add On Clear	Materials for complete the finished dental prosthesis, that complements the appearance of the translucent layer on the outer surface of the artificial tooth

5) Easy On Crystal Glaze, Stain-Khaki, Structure Stain Sky Blue

		
Easy On Crystal Glaze	Stain-Khaki	Structure Stain - Sky Blue

No.	Name	Description
1	Easy On Crystal Glaze	Materials for during the crystallization process by heat treatment of lithium disilicate ceramic prosthesis, the surface of the dental prosthesis is glazed
2	Stain-Khaki	Stain that expresses khaki color on the exterior of dental prosthesis
3	Structure Stain -Sky Blue	Stain that expresses the light blue color and transparent of the enamel layer

6) Easy On Build Up Liquid, Easy On Universal Glaze Liquid (50)

	
<p>Easy On Build Up Liquid</p>	<p>Easy On Universal Glaze Liquid (50)</p>

No.	Name	Description
1	Easy On Build Up Liquid	Liquid material by mixing dental porcelain powder when build up process
2	Easy On Universal Glaze Liquid (50)	If the viscosity of the product increases during use, dilute it

**6. Indications for Use [21 CFR 807.92(a)(5)]**

Easy On Universal Glaze & Stain is suitable for the esthetic individualization of monolithic or minimally reduced dental crown and bridge constructions made of zirconium dioxide or lithium disilicate.

## 7. Technological Characteristics (Equivalence to Predicate Device) [21 CFR 807.92(a)(6)]

There are no significant differences in the technological characteristics of these devices compared to the predicate device which adversely affect safety or effectiveness. A table comparing the key features of the subject device and the predicate device is provided below table.

**[Table. Comparison of Proposed Device to Predicate Device]**

	Proposed Device	Predicate Device	Note
K Number	-	K193588	
Manufacturer	Doctus Global	Dental Direkt GmbH	
Product name	Easy On Universal Glaze & Stain	DD Contrast	
Product Code	EIH	EIH	Same
Regulation Number	21 CFR 872.6660	21 CFR 872.6660	Same
510(k) Review Panel	Dental	Dental	Same
Indications for Use	Easy On Universal Glaze & Stain is suitable for the esthetic individualization of monolithic or minimally reduced dental crown and bridge constructions made of zirconium dioxide or lithium disilicate.	The DD contrast® veneering ceramics system is suitable for the esthetic individualization of monolithic or minimally reduced dental crown and bridge constructions made of zirconium dioxide or lithium disilicate.	Same
Product for veneering / individualization of dental frameworks	Yes	Yes	Same
Framework material	Zirconium dioxide and lithium disilicate	Zirconium dioxide and lithium disilicate	Same
Minimal amount of fires	1	1	Same
For all sizes of dental frameworks	Yes	Yes	Same
Classification acc. to ISO 6872	Type 1, class 1b	Type 1, class 1b	Same
Material	Feldspar ceramics (Glass Oxide)	Feldspar ceramics	Same
Form	Pastes and liquids	Pastes and liquids	Same
Shades	Different tooth and	Different tooth and	Same

	Proposed Device	Predicate Device	Note
	individualization shades	individualization shades	
Physical properties	Conform to ISO 6872:2015	Conform to ISO 6872:2015	Same
Flexural strength	≥ 50 MPa	≥ 50 MPa	Same
Single use	Yes	Yes	Same
Sterility	Non-sterile	Non-sterile	Same

Doctus Global believes that the new product Easy On Universal Glaze & Stain is substantially equivalent to the predicate device when used as instructed by knowledgeable and trained dental personnel. There is no change of the intended use of the new device and no difference in fundamental scientific technology. The new device is made from the same materials as the predicate device. The new device was verified in accordance with the abovementioned FDA recognized standards.

In conclusion, Easy On Universal Glaze & Stain is substantially equivalent to the legally marketed predicate device.

## 8. Non-Clinical Test Summary [21 CFR 807.92(b)(1)]

The following data were provided in support of the substantial equivalence determination:

### 1) Bio-compatibility

Bio-compatibility test is performed according to below:

- 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
- ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 10993-3:2014 Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
- ISO 10993-6:2016 Biological evaluation of medical devices — Part 6: Tests for local effects after implantation
- ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
- ISO 7405:2018 Dentistry — Evaluation of biocompatibility of medical devices used in dentistry

### 2) Performance Test



The performance tests were performed according to ISO 6872:2015 Dentistry - Ceramic materials, and the test results showed that the proposed device meets the requirements specified in the standard.

ISO 6872 Cl.	Test item	Requirements
5.1	Uniformity	The color shall be uniformly dispersed
5.2	Extraneous materials	It shall be free from extraneous materials
5.3	Mixing and condensation	It shall neither form lumps, nor granules during mixed, and it shall neither crack, nor crumble during drying.
7.2	Radioactivity	Uranium <sup>238</sup> shall be less than 1.0 Bq/g
7.3	Flexural strength	It shall not be less than 50MPa
7.4	Linear thermal expansion coefficient	It shall be within $(12.0 \pm 0.5) \times 10^{-6} K^{-1}$
7.5	Glass transition temperature	It shall be within $(560 \pm 20)^\circ C$
7.6	Chemical solubility	The mass loss shall be less than $100 \mu g/cm^2$

The requirements for other test items are as follows.

Test item	Requirements
Appearance	When tested by visual inspection, it shall be free from extraneous materials and suitable for use.
Package	When tested by visual inspection, it shall be no damage, extraneous materials and the other harmful defects for usage.
Weight	When measured the weight using a balance, the tolerance shall be within $\pm 5\%$ .

## 9. Clinical Test Summary [21 CFR 807.92(b)(2)]

Clinical testing is not included in this submission.

## 10. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

There are no significant differences between proposed device and the predicate devices that would adversely affect the use of the product. It is substantially equivalent to these devices in indications for use and technology characteristics.



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## **11. Conclusion [21 CFR 807.92(b)(3)]**

In accordance with the Federal Food & Drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, concludes that the Easy On Universal Glaze & Stain is substantially equivalent in safety and effectiveness to the predicate device as described herein.