DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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SwissMediTec GmbH
Kurosh Sohi
Senior Director/ QA
Gfellen 26
Finsterwald, 6162 Luzern
SWITZERLAND

October 3, 2017

Re: K170873
Trade/Device Name: Medi Galaxy Flow, Medi Classic, Medi Pearl, Medi Jupiter, Medi Opaque Plus, Medi Opaque Posterior, Medi White Pearl
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: July 21, 2017
Received: August 2, 2017

Dear Kurosh Sohi:

This letter corrects our substantially equivalent letter of October 2, 2017.

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 (DICE) 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 (DICE) 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,

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

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)*
K170873

Device Name
Medi Galaxy Flow, Medi Classic, Medi Pearl, Medi Jupiter, Medi Opaque Plus, Medi Opaque Posterior, Medi White Pearl

Indications for Use *(Describe)*
1) Direct anterior and posterior restorations (including occlusal surfaces)
2) Direct veneers
3) Correction of tooth position and tooth shape
4) Indirect restorations including inlays, onlays and veneers
5) Intraoral repairs of fractured restorations
6) Core build-ups
7) Splinting

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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Section 5.1 Device Description

The subject devices (**Medi galaxy Flow, Medi Classic, Medi Pearl,Medi Jupiter,Medi Opaque Plus, Medi Opaque Posterior,Medi White Pearl**) are visible light-cure, radiopaque restorative material (Composite) with high polishingability, excellent physical properties and are designed for anterior and posterior restorations. The subject devices formulated from multifunctional methacrylate monomer-based resin, photo initiator, silanated inorganic filler and pigments. Available in multiple shades. These restoratives provides high strength and low wear for durability. They are packaged in traditional syringes and Pre-Loaded Tips.

(a) Identification.

Tooth shade resin material is a device composed of materials such as bisphenol-A glycidyl methacrylate (Bis-GMA) intended to restore carious lesions or structural defects in teeth.

They are classified into tooth shade resin material (21 CFR section 872.3690, Product code: EBF) according to CFR-872.

(b) Classification. Class II.

Physical and mechanical properties of the subject devices (**Medi galaxy Flow, Medi Classic, Medi Pearl,Medi Jupiter,Medi Opaque Plus, Medi Opaque Posterior,Medi White Pearl**) are evaluated according to **ISO** 4049: **2009** (Dentistry - Polymer-based restorative materials). According to **ISO** 4049: **2009,** the subject devices are classified into the following:
- Type **II:** Polymer-based restorative materials;
- Class **2**: materials whose setting is effected by light;

- Group **I:** materials whose use requires the energy to be applied intra-orally.

Section 5.2 Indication for Use Statement

The **Indication for Use** of the subject devices (**Medi galaxy Flow, Medi Classic, Medi Pearl,Medi Jupiter,Medi Opaque Plus, Medi Opaque Posterior,Medi White Pearl**) were prepared based on that of the predicate device. Therefore, the intended purposes of the subject devices are substantially equivalent to those of the predicate device (**Clearfil Majesty ES-2**).
They are intended for the following indications:
1-Direct anterior and posterior restorations teeth (including occlusal surfaces)
2-Direct veneers
3-Correction of tooth position and tooth shape.
4-Indirect restorations including inlays,onlays and veneers

5-Intraoral repairs of fractured restorations

6-Core build-ups

7-Splinting

Technological characteristics of device
It can be said that subject devices (**Medi galaxy Flow, Medi Classic, Medi Pearl,Medi Jupiter,Medi Opaque Plus, Medi Opaque Posterior,Medi White Pearl**), are substantially equivalent in performance as well as those of the predicate device with the following characteristics:

1-Chemical ingredients
All the chemical ingredients of the subject devices (**Medi galaxy Flow, Medi Classic, Medi Pearl,Medi Jupiter,Medi Opaque Plus, Medi Opaque Posterior,Medi White Peal**) are used in the predicate devices, indicating the subject devices are substantially equivalent to the predicate device.

Regarding the predicate device, there have not been any reported problems or recalls according to the post-market adverse event reporting requirements in the **US.**

2-Performance
Regarding the comparison with the predicate device according to **ISO** 4049: **2009,** the subject devices (**Medi galaxy Flow, Medi Classic, Medi Pearl, Medi Jupiter,Medi Opaque Plus, Medi Opaque Posterior, Medi White Pearl**) and the predicate device comply with **ISO** 4049:**2009** indicating that the subject devices are substantially equivalent in performance to the predicate device (**Clearfil Majesty ES-2**).

3-Biocompatibility
All the chemical ingredients of the subject devices(**Medi galaxy Flow, Medi Classic, Medi Pearl,Medi Jupiter,Medi Opaque Plus, Medi Opaque Posterior,Medi White Pearl**), have been used in the predicate device.
Regarding the predicate device, there have not been any reported problems or recalls according to the post-market adverse event reporting requirements in the US. Accordingly, it was considered that the subject devices are substantially equivalent in performance to the predicate device.

Section 5.3 Substantial Equivalence Discussion

The subject devices (**Medi galaxy Flow, Medi Classic, Medi Pearl,Medi Jupiter,Medi Opaque Plus, Medi Opaque Posterior,Medi White Pearl**) are similar to predicate device in terms of indication for use, design, chemical composition, physical properties and performance etc. The subject devices consist of multifunctional methacrylate resin base composite, as is the predicate device (Clearfi Majestx ES-2). The compressive strength, flexural strength, depth of cure, particle size range and radiopacity of subject devices and Predicate Device **Clearfil Majesty ES-2** fall within very similar values (**Table.1**).
The physical properties and performance of subject devices are not significantly different from the predicate device (**Clearfil Majesty ES-2**), as indicated by non-clinical performance testing. The variety of shades and sizes are different between subject device and predicate device.

Table 1 Comparison of Subject Devices and Predicate Devices

Descriptive Information	Subject Devices	Predicate Device	Summary
Device Name	• Medi galaxy Flow • Medi Classic • Medi Pearl • Medi Jupiter • Medi Opaque Plus • Medi Opaque Posterior • Medi White Pearl	• Clearfil Majesty ES-2	-
Manufacturer	Swissmeditec GmbH	Kuraray Noritake Dental Inc.	-
510(k)	To be assigned	K121583	-
Application Properties/ Delivery form	It is packaged in traditional syringes or Pre-loaded tips (PLTs) **Accessory:** Shade Guide	It is packaged in traditional syringes or Pre-loaded tips (PLTs) **Accessory:** Shade Guide	-
Intended user	Dental professionals	Dental professionals	-
Indications for	1-Direct anterior and posterior restorations teeth (including occlusal surfaces) 2-Direct veneers 3-Correction of tooth position and tooth shape.	1- Direct restorations for all cavity classes in anterior and posterior teeth 2- Direct veneers 3- Correction of tooth position and tooth shape (e.g. diastema closure,	Indications of the subject devices are the

use	4-Indirect restorations including inlays, onlays and veneers 5-Intraoral repairs of fractured restorations 6-Core build-ups 7-Splinting	dwarfed tooth, etc.) 4-Intraoral repairs of fractured restorations	same as the predicate device.
Design	Screw top 2.5ml(4.5g) syringe and Pre Loaded Tube 0.3 g	Screw top 2.0ml (3.6g) syringe and Pre Loaded Tube 0.25 g	Subject devices contain 25% more composite than predicate device but have the same design
Composition of Materials	Methacrylate-based resin, photo initiator, fillers and pigments.	Methacrylate-based resin, photo initiator, fillers and pigments.	Chemically similar to the predicate device.
Physical and Performance Properties	1-Radiopacity: 2.10 (±0.04) mm Al 2-Compressive strength: 338-352 (±0.08) MPa 3-Elasticity modulus: 15.1(±0.07) GPa 4-Fracture Toughness: 1.71 (±0.09) MPa.m1/2 5-Surface Hardness (KHN): 75.03 ± 2.10 6-Flexural Strength: 131 (±14) MPa 7-Flexural Modulus: 10.6 (±0.6) MPa 8-Water Sorption: 23.1 (±2.1) µg/mm3 9-Water Solubility: 1.0 (±0.7) µg/mm3 10-Intensity for curing (for photo - initiated resins):1200-2000 mW/cm^2 11-wavelength for curing (for photoinitiated resins):400-520 nm 12-Maximum absorbance 450-480 **(468)**nm 13-Depth of Cure: 2.22 (±0.03) mm 14-Curing time: 40 s/2mm	1-Radiopacity: 2.13 (±0.08) mmAl 2-Compressive strength: 341(±0.11) MPa 3-Elastic modulus: 14.8(±0.06) GPa 4-Fracture Toughness: 1.68 (±0.10) MPa.m1/2 5-Surface Hardness (KHN): 71.07 ± 2.24 6-Flexural Strength: 127 (±10) MPa 7-Flexural Modulus: 11.6 (±0.8) MPa 8-Water Sorption: 19.3 (±1.9) µg/mm3 9-Water Solubility: 0.8(±0.8) µg/mm3 10-Intensity for curing (for photo - initiated resins): 1200-2000 mW/cm^2 11-wavelength for curing (for photoinitiated resins) :400-520nm 12-Maximum absorbance 450-480 **(468)** nm 13-Depth of Cure: 2.40 (±0.02) mm 14-Curing time: 40 s/2mm	Physical and performance properties data support substantial equivalence of the Subject devices when compared to the predicate device.
FDA Recognized Standards	**ISO** 4049: **2009**	**ISO** 4049: **2009**	4-181
Shelf Life	36 month shelf life, room temperature	36 month shelf life, room temperature	Same

CONCLUSIONS

The indications and technological characteristics of subject devices (**Medi galaxy Flow, Medi Classic, Medi Pearl,Medi Jupiter,Medi Opaque Plus, Medi Opaque Posterior,Medi White Pearl**) are

substantially equivalent to predicate device(**Clearfil Majesty ES-2**). Therefore, subject devices are substantially equivalent to the identified predicate device.
Regarding the predicate device, there have not been any reported problems or recalls according to the post-market adverse event reporting requirements in the US. Accordingly, it was considered that the subject devices are Substantially Equivalent in effectiveness to the predicate device

Section 5.4 Technological Characteristics

It can be said that subject devices (**Medi galaxy Flow, Medi Classic, Medi Pearl,Medi Jupiter,Medi Opaque Plus, Medi Opaque Posterior,Medi White Pearl**), are substantially equivalent in performance as well as those of the predicate device with the following characteristics:

1-Chemical ingredients
All the chemical ingredients of the subject devices (**Medi galaxy Flow, Medi Classic, Medi Pearl,Medi Jupiter,Medi Opaque Plus, Medi Opaque Posterior,Medi White Pearl**) are used in the predicate devices, indicating the subject devices are substantially equivalent to the predicate device.

Regarding the predicate device, there have not been any reported problems or recalls according to the post-market adverse event reporting requirements in the **US.**

2-Performance
Regarding the comparison with the predicate device according to **ISO** 4049: **2009,** the subject devices(**Medi galaxy Flow, Medi Classic, Medi Pearl,Medi Jupiter,Medi Opaque Plus, Medi Opaque Posterior,Medi White Pearl**) and the predicate device comply with **ISO** 4049:**2009** indicating that the subject devices are substantially equivalent in performance to the predicate device.

3-Biocompatibility
All the chemical ingredients of the subject devices(**Medi galaxy Flow, Medi Classic, Medi Pearl,Medi Jupiter,Medi Opaque Plus, Medi Opaque Posterior,Medi White Pearl**), have been used in the predicate device.
Regarding the predicate device, there have not been any reported problems or recalls according to the post-market adverse event reporting requirements in the US. Accordingly, it was considered that the subject devices are substantially equivalent in performance to the predicate device.

4-Substantial Equivalence Discussion
The subject devices (**Medi galaxy Flow, Medi Classic, Medi Pearl, Medi Jupiter, Medi Opaque Plus, Medi Opaque Posterior,Medi White Pearl**) are similar to predicate device in terms of indication for use, design, chemical composition, physical properties, performance, etc. The subject devices (**Medi galaxy Flow, Medi Classic, Medi Pearl,Medi Jupiter,Medi Opaque Plus, Medi Opaque Posterior,Medi White Pearl**) consist of multifunctional methacrylate resin base composite , as is the predicate device. The compressive strength, flexural strength, depth of cure, particle size range and radiopacity of subject devices and Predicate Device **Clearfil Majesty ES-2** fall within very similar values. The physical properties and performance of subject devices are not significantly different from the predicate device (**Clearfil Majesty ES-2**), as indicated by non-clinical performance testing. The variety of shades and sizes are different between subject device and predicate device.

Section 5.5 Performance Data

Curing time evaluated according to ISO 10650-1

Light Source	Curing time/sec.	Wavelength range and light intensity	Depth of cure/mm
	20		1.5

	40		2.0
	20		1.5
	40		2.0

Light source	Cure time/Sec.	Depth of cure/mm	
		A1, A2, A3, A3.5, A4, B1, B2, B3, C2, C3, C4, D2, D3, D4, BL1, BL2, E1, E2, E3	OA2, OA3, OA4
Conventional Halogen	20	1.5	1.0
LED	20	1.5	1.0