May 6, 2020

Dentkist, Inc.
% Peter Chung
President
Plus Global
300 Atwood St.
Pittsburgh, Pennsylvania 15213

Re: K193496
Trade/Device Name: CharmFil
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: January 30, 2020
Received: February 6, 2020

Dear Peter 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. 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193496

Device Name
CharmFil

Indications for Use *(Describe)*
CharmFil is indicated for following restorative applications.
1. Class I, II, V restorations of posterior teeth
2. Class III, IV, V restorations of anterior teeth
3. Cervical cavities or defects involving root surfaces

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

1. Applicant

1) Company : Dentkisk, Inc
2) Address : (Dangjeong-dong) 3, Nongshim-ro, Gunpo-si, Gyeonggi-do, Korea
3) Tel : 82-31-458-2822
4) Fax : 82-31-458-1312
5) Prepared date : May. 06, 2020
5) Contact person : Peter Chung, 412-512-8802
6) Contact person address : 300, Atwood Street, Pittsburgh, PA, 15213, USA
7) Submission date : May. 06, 2020
8) Contact person : J. Y. Lee (jylee@dentkist.com)

2. Device Information

1) Trade name : CharmFil
2) Common name : Tooth Shade Resin Material
3) Classification name : Material, Tooth Shade, Resin
4) Product code : EBF
5) Regulation number : 872.3690
6) Class of device : Class II
7) Panel : Dental
8) Model codes : CharmFil Plus, CharmFil Plus Caps, CharmFil Flow

3. The legally marketed device to which we are claiming equivalence

Predicate device : K042124 DenFil, Vericom Co., Ltd.
Reference device : K120768 EsFlow, Spident Co., Ltd.

4. Device description

This device is light curing dental filling material for dental surgery treatment and type 1, class 2, group 1 according to ISO 4049 classification. It is made in the form of paste and filled in syringe. When you use the product, press out the content in the syringe by screw. It is used to restore a cavity as taking out from it as much as you need with an instrument. It is dental filling material for restoring the cavities.

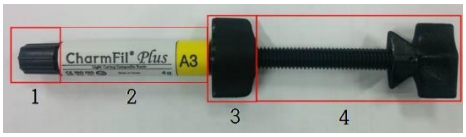
5. Indications for Use Statement

CharmFil is indicated for following restorative applications.

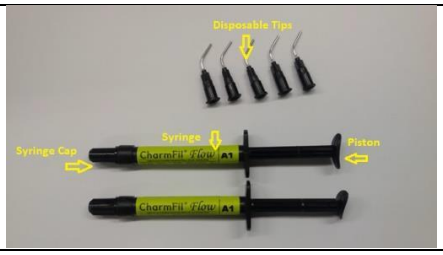
1. Class I, II, V restorations of posterior teeth
2. Class III, IV, V restorations of anterior teeth
3. Cervical cavities or defects involving root surfaces

6. Predicate device comparison table

1) CharmFil Plus and DenFil Flow

Manufacturer	Denkist, Inc.	VERICOM Co., Ltd.	Gap analysis
510(k) No.	K193496	K042124	N/A
Indications for use Statement	The CharmFil are intended for class I, II, V of posterior teeth, class III,IV, V of anterior teeth and cervical cavities involving root surfaces.	The DenFil are intended for class I, II, V of posterior teeth, class III,IV, V of anterior teeth and cervical cavities involving root surfaces.	Same
Classification name	Tooth shade resin material	Tooth shade resin material	Same
Trade name	CharmFil Plus, CharmFil Plus Caps	DenFil	N/A
Appearance			Similar
Product configuration	Syringe, Disposable tip	Syringe, Disposable tip	Same
Expiration date	2 years	2 years	Same
Standard conformed	ISO 4049		N/A
Biocompatibility	Yes	Yes	Same
Principle of operation	Manual	Manual	Same

2) CharmFil Flow and EsFlow

Manufacturer	Denkist, Inc.	Spident Co., Ltd.	Gap analysis
510(k) No.	K193496	K120768	N/A
Indications for use Statement	The CharmFil are intended for class I, II, V of posterior teeth, class III,IV, V of anterior teeth and cervical cavities involving root surfaces.	The EsFlow are intended for use in various dental procedures, including direct anterior and posterior restorations, blocking out cavity undercuts before fabrication indirect restorations, and repair of porcelain / composite materials.	Similar
Classification name	Tooth shade resin material	Tooth shade resin material	Same
Trade name	CharmFil Flow	EsFlow	N/A
Appearance			Similar
Product configuration	Syringe, Disposable tip	Syringe, Disposable tip	Same
Expiration date	2 years	2 years	Same
Standard conformed	ISO 4049	ISO 4049 EN 1641	N/A
Biocompatibility	Yes	Yes	Same
Principle of operation	Manual	Manual	Same

CharmFil Plus and CharmFil Plus Caps contains the same materials with same amount. Only the using method is different because the CharmFil Plus Caps is manufactured capsule-like shape.

The CharmFil has the similar device characteristics as the predicate device and reference device, the DenFill and EsFlow; intended use, material, chemical composition, design and use concept are similar.

The differences between CharmFil and the predicate device and reference device has been subjected to performance and product validations testing prior to release. Tests have been performed to ensure the devices comply to applicable industry and US regulations.

An extensive review of literature pertaining to the safety and biocompatibility of CharmFil has been conducted. Appropriate safeguards have been incorporated in the design of CharmFil.

Although some of the materials used are different, the materials for performance are all the same and all of the other materials meet biocompatibility criteria. The methods of use and physical and chemical performance are similar and all meet the appropriate criteria.

7. Performance testing

No.	Test item	Requirements	Result
Physical and chemical property (Polymerization time) / ISO 4049			
1	Color	The exposed and unexposed halves of each of the specimens and the unirradiated specimen for any color difference	Suitable
2	Appearance test	Shall be homogeneous and co substances are observed	Suitable
3	Quantity test	No less than ±5% that claimed value	Suitable
4	Sensitivity to ambient light	After exposure for 60sec, it should be not any charge of consistency	Suitable
5	Polymerization depth	After exposure for 1 minute, Opaque shade is more than 1mm, and other shades is over 1.5mm	Suitable
6	Flexural strength	+80 Mpa	Suitable
7	Water solubility	- 40 μg/㎟	Suitable
8	Water sorption	-7.5 μg/㎟	Suitable
9	Radio-opacity	Shall be equal to or greater than that of the same thickness of aluminum and no less than 0.5mm	Suitable
10	Color stability	The exposed and unexposed halves of each of the specimens and the unirradiated specimen for any color difference	Suitable
Elution substance test			
11	Character test	It should be homogeneous and appropriate. Without any foreign substance, impurity, floating substance.	Suitable
12	pH	pH difference ≤ 1.5	Suitable
13	Heavy metal (Lead content)	It should be less ticker than comparison liquid. (-100ppm)	Suitable
14	Permanganic acid calcium reduction nature substance	Difference of consumption of permanganic acid calcium≤ 2.0 ㎖	Suitable
15	Evaporation residue	Difference of residues ≤ 1.0 ㎎	Suitable
16	Ultraviolet rays absorption spectrum	Max. absorbance numerical value ≤ 0.1	Suitable
Biological safety test (Biocompatibility, irritation)			
17	Cell toxicity test	0~1 (None~Mild)	Suitable
18	Short period whole body	During the period of examination	Suitable

	toxicity test (Oral route)	there should not be odd or dead on it.	
19	Oral route impetus test	Compare it with contrast product, stimulus response should not appear on mouth mucous	Suitable
20	Endo-toxin test	According to the method of examination, it should be appropriate.	Suitable

8. Conclusion:

The Device is investigated for function to compare the operation of function between CharmFil and predicate devices.

Comparison results demonstrate that the specifications and performance of the device are same as functional as the legally marketed predicate device.

Therefore, it is concluded that CharmFil is substantially equivalent to the legally marketed predicate device.