DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 13,2016

Dentkist, Inc.
c/o Mr. Peter Chung
President
Plus Global
300 Atwood Street
Pittsburgh, Pennsylvania 15213

Re: K152766
Trade/Device Name: CharmFlex®
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: ELW
Dated: February 1, 2016
Received: February 5, 2016

Dear Mr. Peter Chung:

This letter corrects our substantially equivalent letter of March 8, 2016. 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); 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), 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" (21CFR 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

for Erin I. Keith, M.S.
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)*
K152766

Device Name
CharmFlex®

Indications for Use *(Describe)*
- Impression material in a dual phase impression technique
- Precise duplication of models
- Capturing multiple unit impressions

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(k) Summary

[as required by 807.92(c)]

1. Applicant

1) Company : Dentkist, 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 : March 7, 2016
5) Contact person : Peter Chung, 412-687-3976
6) Contact person address : 300, Atwood Street, Pittsburgh, PA, 15213, USA
7) Submission date : Sep. 18, 2015

2. Device Information

1) Trade name : CharmFlex®
2) Common name : Dental Impression Materials
3) Classification name : Impression Material
4) Product code : ELW
5) Regulation number : 872.3660
6) Class of device : Class II
7) Panel : Dental
8) Model codes : 13 model codes including CharmFlex® Putty
   - CharmFlex® Putty
   - CharmFlex® Putty Green
   - CharmFlex® Putty Soft
   - CharmFlex® Heavy cartridge type
   - CharmFlex® Heavy tube type
   - CharmFlex® Regular
   - CharmFlex® Denture
   - CharmFlex® Light LV
   - CharmFlex® Light XLV
   - CharmFlex® Light Premium
   - CharmFlex® Bite
   - CharmFlex® Bite Clear
   - CharmFlex® Bite Fast

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

Primary Predicate:
K103164 Vonflex™ Heavy/Vonflex™ Light

Reference Predicates:
K091267 Vonflex™ Putty
K140966 Vonflex™ Bite
Manufacutred by VERICOM CO.,LTD.

4. Device description

CharmFlex is impression material. It has 5 types: Putty, Regular, Light, Heavy, Bite.

1) CharmFlex®Putty/ CharmFlex®Putty Green/ CharmFlex®Putty Soft
   CharmFlex®Putty consists of various Putty-bodies type and dental addition silicone impression material made by polymerization as a mixture of Base and Catalyst. In dental treatment, an impression material used to record oral tissue anatomy.
   CharmFlex®Putty has viscosity of putty consistency classification according to type 0

ISO 4823 classification. Packaging consists of two putty systems which are supplied by in two jars, the one is base and another is catalyst. This product is used for two step impression and the material for the first impression is for recording oral tissue anatomy. Base and catalyst of impression are packed separately

2) CharmFlex®Heavy cartridge type/ CharmFlex®Heavy tube type
CharmFlex® Heavy series are hydrophilic vinyl polysiloxane impression materials type of Heavy-bodies. It is used for the one-step impressions teeth or individual tooth in the mouth. CharmFlex®Heavy as the additional polymerization silicone type is rubber impression materials that registers oral tissue anatomy. It is used with Light-body for impression taking. Packages are cartridge type which is supplied by from of two syringes. This product is used for the first or second impression taking of whole teeth or individual tooth in mouth before the final impression taking. It is silicone based dental rubber impression materials.

3) CharmFlex®Regular/ CharmFlex®Denture/ CharmFlex®Light LV/ CharmFlex®Light XLV/ CharmFlex®Light Premium
CharmFlex®Light series are hydrophilic vinyl polysiloxane impression material type of LightLV, Regular and LightXLV. It is used for the one-step or two-step impression taking of teeth or individual tooth in the mouth. CharmFlex® Light LV/Light XLV/Regular series as the additional polymerization silicone type are rubber impression materials that records oral tissue anatomy. Packages are cartridge type which is supplied by from of two syringes. This product is used for the first or second impression taking of teeth or individual tooth in mouth before the final impression taking. It is silicone based dental rubber impression materials.

4) CharmFlex®Bite/ CharmFlex®Bite Clear/ CharmFlex®Bite Fast
CharmFlex®Bite series are bite registration impression material to measure of the occlusal surface, impression of the teeth for a three-dimension position of the mandible in relation to the maxilla. It has a short polymerization time and a high final hardness. Making it suitable for bite registration.

5. Indications for Use :

- Impression material in a dual phase impression technique
- Precise duplication of models
- Capturing multiple unit impressions

6. Performance data:

Bench test

Test items	Standards
Appearance test	ISO 4823 Dentistry-Elastomeric impression materials
Weight test	
Component test	
Working time test	
Minimum strength test	
Hardness test	
Liniear dimensional chage test	
Consistency	
Working time	
Detail reproduction	
Compatibility with gypsum	
Elastic recovery	
Strain-in-compression	

Biocompatibility Testing

- Cytotoxicity according to ISO 10993-5
- Systemic Toxicity according to ISO 10993-11
- Oral Mucosa Irritation Testing according to ISO 10993-10
- Sensitization Testing according to ISO 10993-10

Shelf-Life Validation

Accelerated shelf-life testing was conducted according to ASTM 1980 to confirm the shelf-life of the subject device.

FDA Guidance Document

Conformance to the recommendation in the FDA Guidance Document for Dental Impression Materials.

7. Predicate device comparison table

1) CharmFlex Heavy / CharmFlex Light LV / CharmFlex Light XLV / CharmFlex Regular

	Subject Device	Predicate Device
Company	Dentkist, Inc.	VERICOM Co., Ltd.
Device Name	CharmFlex Heavy / CharmFlex Regular / CharmFlex Denture / CharmFlex Light LV / CharmFlex Light XLV / CharmFlex Light Premium	Vonflex™ Heavy / Vonflex™ Light / Vonflex™ Medium
510(k) #	N/A	K103164
Classification	Material, Impression	Material, Impression
Product Code	ELW	ELW
Regulation	21 CER 872.3660	21 CER 872.3660
Indications for Use	- Impression material in a dual phase impression technique - Precise duplication of models - Capturing multiple unit impressions	- Impression material in a dual phase impression technique - Precise duplication of models - Capturing multiple unit impressions - All impression techniques where the operator needs a heavy or low viscosity material

Method of manipulation	1. CharmFlex Heavy 1) **Tube type** : Squeeze equal volume of Base and Catalyst (1:1) and mix quickly with a tool for 1'30" and load Heavy-body on the tray. **Cartridge type** : Apply Heavy-body on the tray. 2) Inject Light-body on tray and directly onto the teeth. (Intra oral tip is used to inject around the teeth.) 3) Set the tray in the mouth, keep the material until it is perfectly set in mouth. 4) After impression material is perfectly set, store it in room for 30 minutes. 2. CharmFlex Regular / CharmFlex Denture / CharmFlex Light LV / CharmFlex Light XLV / CharmFlex Light Premium 1) Apply the materials onto the tray of putty (2-step) / Heavy Body (1-step) depending on techniques being used. 2) Set the tray in the mouth, keep the material until it is perfectly set in mouth. 3) After impression material is perfectly set, store it in room for 30 minutes.	1. Cartridge-Light, Medium, Heavy Place the cartridge of Vonflex S into a impression gun. Squeeze the cartridge several times to extrude the material. Dispense a small amount of impression material before installing a mixing tip to ensure even flow from each side of the cartridge. 2. Tube-Heavy Squeeze the same amount of Vonflex S, Catalyst and Base on a mixing pad. Mixing ratio is 1 volume Base: 1 volume Catalyst for Vonflex S. Mix them quickly within 30 seconds with spatula until two different colors are mixed into the same color perfectly. 3. Prior to taking the impression, remove any residue of pollutants in the oral by rinsing and dry completely. 4. Put Medium or Heavy into the tray, and then load Light body with mixing tip on it. 5. Load Light body with a mixing tip on the preparations inside of a mouth. And seat the loaded tray on the preparations to get a final impression 6. after setting the impression, remove the tray from the mouth. And rinse it with water or disinfect it by using any ADA accepted liquid disinfectant.
Chemical composition	- Vinyl Siloxane - Hydrogen Siloxane - Silicon dioxide	- Vinyl Siloxane - Hydrogen Siloxane - Fumed Silica

	- Calcium silicate - Mineral Oil - Pigments	- Organo Platinum Complex - Polyethylene glycol dodecyl ether - Pigments
Flow properties	Low viscosity Heavy(high viscosity)	Light(Low viscosity) Medium(medium viscosity) Heavy(high viscosity)
Viscosity	48mm Heavy(34.25mm)	Light(42mm),Medium(36mm),Heavy(33mm)
Wettability	High, Heavy(Low)	Light(high), Regular(medium), Heavy(Low)
Working time	1.CharmFlex Heavy cartridge type: 1'30" 2.CharmFlex Heavy tube type: 2' 3.CharmFlex Regular/ CharmFlex Denture/CharmFlex Light LV/ CharmFlex Light XLV/CharmFlex Light Premium: 2'~2'30"	Light: 1'30''~2'30'' Medium, Heavy: 1'30"~2'15"
Setting time	2'~4'	4'
Mechanical strength	55~65 Heavy(62±2)	Light(50±2), Medium(55±2), Heavy(64±2)
Working humidity	50±10%	50±10%
Dimension accuracy	20 ㎛	22 ㎛
Strain in compression	4.0~5.0%	4.0~5.0%
Consistency	48mm Heavy(34.25mm)	Light(42mm),Medium(36mm),Heavy(33mm)
Safety	safe	safe
Compatibility with the die and cast materials	20 ㎛	22 ㎛
Keeping qualities	cool and dry place (18~24 ℃/64~75 ℉)	At a cool place(2~24℃)
Curve of the shrinkage	No data	No data
Use	Dentist, Dental specialist	Dentist, Dental specialist

2) CharmFlex Putty / CharmFlex Putty Green / CharmFlex Putty Soft

	Subject Device	**Predicate Device**
Company	Dentkist, Inc.	VERICOM Co., Ltd.
Device Name	CharmFlex Putty / CharmFlex Putty Green / CharmFlex Putty Soft	VonflexS™ Putty
510(k)	N/A	K091267
Classification	Material, Impression	Material, Impression
Product Code	ELW	ELW
Regulation	21 CER 872.3660	21 CER 872.3660
Indications for Use	- Impression material in a dual phase impression technique - Precise duplication of models - Capturing multiple unit impressions	- Impression material in a dual phase impression technique - Precise duplication of models - Capturing multiple unit impressions - All impression techniques where the operator needs a heavy or low viscosity material
Method of manipulation	1. Take out the same amount of Base and Catalyst. (1:1 vol.) 2. Knead them properly with hands until a mixed color is attained. Wear disposable vinyl gloves to prevent your hands from incurring an allergic reaction. 3. Apply the mixed material to the tray and set into the mouth. 4. After the material is perfectly set, remove from the mouth. 5. Set the tray with Light-body on the completed Putty-body into the mouth. 6. After the material is perfectly set, store it in room for 30 minutes.	1. Take the same volume of Base and Catalyst with a measuring scoop. Knead them quickly within 30 seconds with clean and dry hands until two different colors are mixed into the same color perfectly. 2. Place Vonflex S putty in to a selected tray and remove the excess of it on the surface. 3. On setting the Vonflex S putty completely, remove the tray from the mouth with moving slightly back and forth. 4. Load Medium or Light body with a mixing tip on the preparations inside of a mouth 5. Put Medium or Light body on pre-impression and seat the loaded tray on the preparations to get a final impression. 6. After setting the impression, remove the tray from the mouth. And rinse it with water or disinfect it by using any ADA accepted liquid disinfectant.
Chemical composition	-Polyvinyl siloxane -Silica	-Polyvinyl siloxane -Silica

Flow properties	High viscosity	High viscosity
Viscosity	25.83mm	26.32mm
Wettability	Low	Low
Working time	1'~1' 30" (26 ℃)	1.30min~2min (23 ℃)
Setting time	2.22'~4'	2.30min~4min
Mechanical strength	65~85	62~75
Working humidity	50%±10	50%±10
Dimension accuracy	30 ㎛	28 ㎛
Strain in compression	3.0~4.0%	3.0~4.0%
Consistency	25.83mm	26.32mm
Safety	safe	safe
Compatibility with the die and cast materials	30 ㎛	28 ㎛
Keeping qualities	cool and dry place (18~24 ℃/64~75 ℉)	At a cool place(2~24℃)
Curve of the shrinkage	No data	No data
Use	Dentist, Dental specialist	Dentist, Dental specialist

3) CharmFlex Bite / CharmFlex Bite Clear / CharmFlex Bite Fast

	Subject Device	**Predicate Device**
Company	Dentkist, Inc.	VERICOM Co., Ltd.
Device Name	CharmFlex Bite / CharmFlex Bite Clear / CharmFlex Bite Fast	Vonflex S™ Bite
510(k)	N/A	K091267
Classification	Material, Impression	Material, Impression
Product Code	ELW	ELW
Regulation	21 CER 872.3660	21 CER 872.3660
Indications for Use	- Impression material in a dual phase impression technique - Precise duplication of models - Capturing multiple unit impressions	- Impression material in a dual phase impression technique - Precise duplication of models - Capturing multiple unit impressions - All impression techniques where the operator needs a heavy or low viscosity material
Method of manipulation	1. Check the expiration date and avoid package contamination. 2. Follow the instructions for use before using. 3. Place a disposable mixing tip on cartridge, and place the cartridge on exclusive mixing gun. 4. Check to be made to mix well during extrusion through the tips. 5. Apply bite registration material directly onto the occlusal surfaces. 6. Set this material to intraoral until the impression material completely polymerized. 7. Remove the set bite registration from intraoral. 8. Make a master cast with a instrument such as a dental knife.	1. Prior to taking Vonflex S Bite, completely remove any residue of pollutants in the oral by rinsing and drying. 2. Place the cartridge of Vonflex S Bite into the impression gun. 3. Dispense a small amount of impression material before installing a mixing tip to ensure even flow from each side of the cartridge 4. Push firmly to attach the mixing tip in the cartridge. Then, rotate the colored collar of the mixing tip 1/4 turns clockwise to the end of the cartridge. 5. Squeeze the handle several times to extrude the material onto occlusal of teeth. Guide patient into centric occlusion to register bite. 6. After the material set, remove it from mouth. If you have extra material after removing the trim undercut. 7. Make sure the bite registration and ready model.
Chemical composition	-Polyvinyl siloxane -Silica	-Polyvinyl siloxane -Silica
Flow properties	High viscosity	High viscosity
Viscosity	32mm	30mm
Wettability	Low	Low
Working time	20~35sec(23℃)	30~45"(23℃)
Setting time	30~60sec	30~90sec
Mechanical strength	89±2	88±2

Working humidity	50%±10	50%±10
Dimension accuracy	1.5 ㎛	2 ㎛
Strain in compression	1.5~2.5%	1.5~2.5%
Consistency	32mm	30mm
Safety	safe	safe
Compatibility with the die and cast materials	1.5 ㎛	2 ㎛
Keeping qualities	cool and dry place (18~24 ℃/64~75 ℉)	At a cool place(2~24℃)
Curve of the shrinkage	brittle feature	brittle feature
Use	Dentist, Dental specialist	Dentist, Dental specialist

The subject device and primary predicate have slightly different Indications for Use language. However, the difference in language does not change the intended use or substantial equivalence.

9. Conclusion:

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

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