DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Spident Co., Ltd.
% Mark Choi
President
Spident Usa Inc.
2115 Linwood Ave, 5f,
Fort Lee, New Jersey 07024

September 30, 2016

Re: K161774
Trade/Device Name: I-Sil
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: ELW
Dated: June 8, 2016
Received: June 28, 2016

Dear Mark Choi:

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 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 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,

Susan Runner DDS, MA

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)*

Device Name
i-Sil

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

[as required by 807.92(c)]

1. Applicant

1) Company : SPIDENT Co.,Ltd.
2) Address : 203 & 312, Korea Industrial Complex, 722, Gojan-Dong, Namdong-Gu, Incheon, Korea
3) Tel : 82-32-819-4570
4) Fax : 82-32-819-4572
5) Prepared date : Jun. 8, 2016
5) Contact person : Mark Choi, Tel 201-944-0511
6) Contact person address : 2115 Linwood Ave, 5F, Fort Lee, NJ 07024, U.S.A
7) Submission date : Jul. 5, 2016

2. Device Information

1) Trade name : i-Sil
2) Common name : Dental Impression Materials
3) Classification name : Material, Impression
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 i-Sil Heavy body fast
    - i-Sil Heavy body fast
    - i-Sil Heavy body regular
    - i-Sil Heavy body jumbo
    - i-Sil Heavy body monophase
    - i-Sil Medium body fast
    - i-Sil Medium body regular
    - i-Sil Medium body jumbo
    - i-Sil Medium body denture
    - i-Sil Light body fast
    - i-Sil Light body regular
    - i-Sil Putty fast
    - i-Sil Putty regular
    - i-Sil Bite

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

K152766, Dentkist, Inc

4. Device description

i-Sil is impression material. It has 5 types: Heavy, Medium, Light, Putty and Bite.

5. Intended 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	

7. Predicate device comparison table

1) Heavy body, Medium body and Light body

	Subject Device	Predicate Device
Company	SPIDENT Co.,Ltd.	Dentkist, Inc.
Device Name	i-Sil Heavy body fast/i-Sil Heavy body regular/i-Sil Heavy body jumbo/i-Sil Heavy body monophase/i-Sil Medium body fast/i-Sil Medium body regular/i-Sil Medium body jumbo/i-Sil Medium body denture/i-Sil Light body fast/i-Sil Light body regular	CharmFlex Heavy / CharmFlex Regular / CharmFlex Denture / CharmFlex Light LV / CharmFlex Light XLV / CharmFlex Light Premium
510(k) #	N/A	K152766
Classification	Material, Impression	Material, Impression
Product Code	ELW	ELW
Regulation	21 CER 872.3660	21 CER 872.3660
Intended 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
Method of manipulation	1. Heavy body **Cartridge type** : 1)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. Medium body, Light body 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. CharmFlex Heavy 1) **Tube type** : Squeeze equal volume of Base and Catalyst (1:1) and mix quickly with a tool for within 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.
Chemical composition	- Siloxane vinyl terminated - Siloxane hydride terminated - Surfactant - Silica - Pigments	- Vinyl Siloxane - Hydrogen Siloxane - Silicon dioxide - Calcium silicate - Mineral Oil - Pigments
Flow properties	Low viscosity	Low viscosity, Heavy(high viscosity)

Working time	1. i-Sil Heavy body series : 1'36" 2. i-Sil Medium body seris : 1'59" 3. i-Sil Light body series : 1'21"	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"
Mixing time test	1. i-Sil Heavy body series : 22.6" 2. i-Sil Medium body series : 38" 3. i-Sil Light body series : 26.8 "	2'~4'
Consistency test report	1. i-Sil Heavy body series : 33.83 mm 2. i-Sil Medium body series : 34.83 mm 3. i-Sil Light body series : 45.33 mm	34.25mm
Detail reproduction	1. i-Sil Heavy body series : pass 2. i-Sil Medium body series : pass 3. i-Sil Light body series : pass	20 ㎛
Linear dimensional change	1. i-Sil Heavy body series : 0.18 % 2. i-Sil Medium body series : 0.20 % 3. i-Sil Light body series : 0.15 %	-0.063 %
Compatibility with gypsum	1. i-Sil Heavy body series : pass 2. i-Sil Medium body series : pass 3. i-Sil Light body series : pass	20 ㎛
Elastic recovery	1. i-Sil Heavy body series : 99.64 % 2. i-Sil Medium body series : 99.6 % 3. i-Sil Light body series : 99.58 %	99.67 %
Strain-in-compression	1. i-Sil Heavy body series : 2.34 % 2. i-Sil Medium body series : 3.29 % 3. i-Sil Light body series : 4.94 %	4.12 %
Keeping qualities	cool and dry place (18~24 ℃/64~75 ℉)	cool and dry place (18~24 ℃/64~75 ℉)
Curve of the shrinkage	No data	No data
Use	Dentist, Dental specialist	Dentist, Dental specialist

2) Putty

	Subject Device	**Predicate Device**
Company	SPIDENT Co.,Ltd.	Dentkist, Inc.
Device Name	i-Sil Putty fast i-Sil Putty regular	CharmFlex Putty / CharmFlex Putty Green / CharmFlex Putty Soft
510(k)	N/A	K152766
Classification	Material, Impression	Material, Impression
Product Code	ELW	ELW
Regulation	21 CER 872.3660	21 CER 872.3660
Intended 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
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 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.
Chemical composition	- Siloxane vinyl terminated - Siloxane hydride terminated - Surfactant - Silica - Pigments	-Polyvinyl siloxane -Silica
Flow properties	High viscosity	High viscosity
Mixing time test	i-Sil Putty fast, i-Sil Putty regular: 41"	30"~40"
Consistency test report	i-Sil Putty fast, i-Sil Putty regular: 31.75 mm	25.83 mm

Detail reproduction	i-Sil Putty fast, i-Sil Putty regular: pass	pass
Linear dimensional change	i-Sil Putty fast, i-Sil Putty regular: 0.35 %	-0.213 %
Compatibility with gypsum	i-Sil Putty fast, i-Sil Putty regular: pass	pass
Elastic recovery	i-Sil Putty fast, i-Sil Putty regular: 99.01 %	99.75 %
Strain-in-compression	i-Sil Putty fast, i-Sil Putty regular: 3.26 %	3.28 %
Keeping qualities	cool and dry place (18~24 ℃/64~75 ˚F)	cool and dry place (18~24 ℃/64~75 ˚F)
Curve of the shrinkage	No data	No data
Use	Dentist, Dental specialist	Dentist, Dental specialist

3) Bite

	Subject Device	**Predicate Device**
Company	SPIDENT Co.,Ltd.	Dentkist, Inc.
Device Name	I-Sil Bite	CharmFlex Bite / CharmFlex Bite Clear / CharmFlex Bite Fast
510(k)	N/A	K152766
Classification	Material, Impression	Material, Impression
Product Code	ELW	ELW
Regulation	21 CER 872.3660	21 CER 872.3660
Intended 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
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. 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.
Chemical composition	- Siloxane vinyl terminated - Siloxane hydride terminated - Surfactant - Silica - Pigments	-Polyvinyl siloxane -Silica
Working time	30" ↑	15" ↑
Flexural strength	pass	pass
Hardness	87.4 HD	pass
Linear dimensional change	0.064 %	pass
Safety	safe	safe
Keeping qualities	cool and dry place (18~24 ℃/64~75 ˚F)	cool and dry place (18~24 ℃/64~75 ˚F)
Curve of the shrinkage	brittle feature	brittle feature
Use	Dentist, Dental specialist	Dentist, Dental specialist

9. Conclusion:

The Device is investigated for substantially equivalent in intended use and technological characteristics to predicate device.

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

Therefore, it is concluded that I-Sil is substantially equivalent to the legally marketed predicate device.