DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 23, 2015

SeilGlobal Co., Ltd.
c/o Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group, USA, Inc.
2651 E Chapman Ave., Suite 110
Fullerton, CA 92831

Re: K143382
Trade/Device Name: DentiAnn Smart Sil
Regulation Number: 21 CFR 872.3660
Regulation Name: Dental Impression Material
Regulatory Class: II
Product Code: ELW
Dated: November 17, 2014
Received: November 25, 2014

Dear Ms. 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. 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K143382

Device Name
DentiAnn Smart Sil

Indications for Use *(Describe)*

DentiAnn Light-body is to be used as a light body material for:
- Two step putty/wash technique
- Single step putty/wash technique
- Functional peripheries
- Reline impressions
- Crown/bridge work
- Inlays, Onlays

DentiAnn Heavy-body is to be used as a heavy body material for:
- Two step putty/wash technique
- Single step putty/wash technique
- Functional peripheries
- Crown/bridge work
- Inlays, Onlays

SmartSil-Putty is to be used as a preliminary material for:
- Two step putty/wash technique
- Single step putty/wash technique
- Functional peripheries
- Crown/bridge work
- Inlays, Onlays

SmartSil-Bite is to be used as a light body material for:
- Making accurate occlusal registrations
- Standards bite registrations in the end bite position.
- Key material for needle point registration.
- Production of small model segments

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)*

510(k) Summary

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: ___Nov 17, 2014___

1. Applicant / Submitter:

SeilGlobal Co., Ltd.
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609-845, Republic of Korea

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2. Submission Correspondent:

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3. Device:

Proprietary Name:	DentiAnn Smart Sil
Common Name:	Dental Impression Material
Classification Name:	Material, Impression
Classification:	Class II, 21 CFR 872.3660
Classification Product Code:	ELW

4. Predicate Device:

BONASIL A+ by DMP, Limited (K102836)

5. Device Description:

DentiAnn Smart Sil is a two component (base paste and catalyst, mixing ratio 1:1) vinyl polysiloxane impression material to be used for impressions, where typically alginates are used. The DentiAnn Smart Sil offers four different viscosities (light, heavy, putty and bite) in delivery systems of cartridges, tubes and/or jars. The device includes accessories such as a mixing tip and a spoon.

6. Intended Use:

DentiAnn Light-body is to be used as a light body material for:
- Two step putty/wash technique
- Single step putty/wash technique
- Functional peripheries
- Reline impressions
- Crown/bridge work
- Inlays, Onlays

DentiAnn Heavy-body is to be used as a heavy body material for:
- Two step putty/wash technique
- Single step putty/wash technique
- Functional peripheries
- Crown/bridge work
- Inlays, Onlays

SmartSil-Putty is to be used as a preliminary material for:
- Two step putty/wash technique
- Single step putty/wash technique
- Functional peripheries
- Crown/bridge work
- Inlays, Onlays

SmartSil-Bite is to be used as a light body material for:
- Making accurate occlusal registrations
- Standards bite registrations in the end bite position.
- Key material for needle point registration.
- Production of small model segments

7. Performance Data(Non-Clinical):

The following properties were tested based on the referenced standards. All the test results support substantial equivalence to the predicate devices.

- ISO 4823 - Component Color Test, Consistency Test, Mixing Time Test, Working Time Test, Detail Reproduction Test, Test for Compatibility with Gypsum, Linear Dimensional Change Test, Elastic Recovery Test, and Strain-in-Compression Test
- ISO 10993-5 – Cytotoxicity Test

- ISO 10993-10 - Skin Sensitization Test, Oral Mucous Irritation Test
- ISO 10993-11 – Acute Systemic Toxicity Test
- Other bench testing – Shelf life, Visual, Capacity, and Package test

8. Substantial Equivalence

The DentiAnn SmartSil is substantially equivalent to the predicate device described herein with respect to intended use, device design, accessory components, and delivery method. Also the curing mechanism of the subject device and the predicate devices is substantially equivalent in principle. Therefore, the subject device and the predicate devices are the same in function, and similar in composition and intended use. This supports that the compatibility and safety of the subject device are substantially equivalent to the predicate devices.

The difference might be the compositions of some materials; however, the biocompatibility and the results of performance testing performed according to ISO 4823 show that this difference does not raise issues in safety and effectiveness.

	Subject Device	**Predicate Device**
510(K) Number	N / A	K102836
Trade Name	DentiAnn SmartSil	BONASIL A+
Manufacturer	SeilGlobal Co., Ltd	DMP, Limited
Product Code	ELW	ELW
Intended Use	DentiAnn Light-body is to be used as a light body material for: ▪ Two step putty/wash technique ▪ Single step putty/wash technique ▪ Functional peripheries ▪ Reline impressions ▪ Crown/bridge work ▪ Inlays, Onlays DentiAnn Heavy-body is to be used as a heavy body material for: ▪ Two step putty/wash technique ▪ Single step putty/wash technique ▪ Functional peripheries ▪ Crown/bridge work ▪ Inlays, Onlays SmartSil-Putty is to be used as a preliminary material for: ▪ Two step putty/wash technique ▪ Single step putty/wash technique ▪ Functional peripheries ▪ Crown/bridge work ▪ Inlays, Onlays	Bonasil A+ Light (light normal set, light fast set) is to be used as a light body material for : ▪ Two step putty/wash technique ▪ Single step putty/wash technique ▪ Functional peripheries ▪ Reline impressions ▪ Crown/bridge work ▪ Inlays, Onlays Bonasil A+ Heavy (heavy normal set, heavy fast set) is to be used as a heavy body material for : ▪ Two step putty/wash technique ▪ Single step putty/wash technique ▪ Functional peripheries ▪ Crown/bridge work ▪ Inlays, Onlays Bonasil A+ Putty (putty normal set, putty fast set, putty soft, putty extra hard, lab putty) is to be used as a preliminary material for : ▪ Two step putty/wash technique ▪ Single step putty/wash technique ▪ Functional peripheries ▪ Crown/bridge work

	SmartSil-Bite is to be used as a light body material for: ▪ Making accurate occlusal registrations ▪ Standards bite registrations in the end bite position. ▪ Key material for needle point registration. ▪ Production of small model segments	▪ Inlays, Onlays Bonasil A+ Bonabite (bonabite fast set) is to be used as a light body material for : ▪ Making accurate occlusal registrations ▪ Standards bite registrations in the end bite position. ▪ Key material for needle point registration. ▪ Production of small model segments
Raw Material	Vinyl polysiloxane	Vinyl polysiloxane
Human Factor	Ready to use dispensing system	Ready to use dispensing system
Biocompatibility	Biocompatible conforming to ISO 10993-1	Biocompatible conforming to ISO 10993-1
Physical Properties	Meets IS0 4823 specifications 1) DentiAnn Light-body - Working time : about180sec - Elastic recovery rate : more than 96.5% - Linear Dimensional change : less than 1.5% - Classification according to the standards (ISO 4823) : Type 3 2) DentiAnn Heavy-body - Working time : about 147sec - Elastic recovery rate : more than 96.5% - Linear Dimensional change : less than 1.5% - Classification according to the standards (ISO 4823) : Type 1 3) SmartSil-Putty - Elastic recovery rate : more than 96.5% - Linear Dimensional change : less than 1.5% - Classification according to the standards (ISO 4823) : Type 0 4) SmartSil-Bite - Working time : about 15sec - Linear Dimensional change : less than 1.5% - Classification according to the standards (ISO 4823) : Type 1 - Hardness : more than 20HD	Meets IS0 4823 specifications 1) Bonasil A+ Light - Working time : about120sec - Elastic recovery rate : more than 96.5% - Linear Dimensional change : less than 1.5% - Classification according to the standards (ISO 4823) : Type 3 2) Bonasil A+ Heavy - Working time : about 120sec - Elastic recovery rate : more than 96.5% - Linear Dimensional change : less than 1.5% - Classification according to the standards (ISO 4823) : Type 1 3) Bonasil A+ Putty - Elastic recovery rate : more than 96.5% - Linear Dimensional change : less than 1.5% - Classification according to the standards (ISO 4823) : Type 0 4) Bonasil A+Bonabite - Working time : about 30sec - Linear Dimensional change : less than 1.5% - Classification according to the standards (ISO 4823) : Type 2 - Hardness : more than 20HD
Mixing ratio	1:1	1:1
Sterility	Non-sterile	Non-sterile

9. Conclusion:

Based on the testing results, SeilGlobal Co., Ltd. concludes that the DentiAnn Smart Sil is substantially equivalent to the predicate devices.