



Food and Drug Administration
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November 13, 2015

Korea Engineering Plastics Co., Ltd.
c/o Mr. Charlie Mack
Principal Engineer
International Regulatory Consultants
12226 Washington Lane
Parker, Arizona 85344

Re: K152270

Trade/Device Name: Smilestone[®]

Regulation Number: 21 CFR 872.3690

Regulation Name: Denture Relining, Repairing, Rebasing Resin

Regulatory Class: II

Product Code: EBI

Dated: August 31, 2015

Received: September 10, 2015

Dear Mr. Mack:

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 yours,

 Tina
Kiang -S

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

Indications for Use

510(k) Number (if known)

K152270

Device Name

Smiletone®

Indications for Use (Describe)

Smiletone® (denture base resin) is a thermoplastic resin that is intended to be used in fabrication of removable full and partial dental prosthesis, as well as occlusal splints and night guards. The product is based on a compounded mixture of polyamide and pigments.

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:

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“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

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

Date: July 1, 2015

1. Company and Correspondent making the submission:

Name – KOREA ENGINEERING PLASTICS Co., Ltd.

Address – 216, 217, 218, B Bldg, 17, Gosan-ro 148 beon-gil, Gunpo-si, Gyeonggi-do, 435-833, Korea

Phone : +82-31-689-3615

Fax : +82-31-8086-8285

Contact – Mrs. Song-yi Chong

Internet – <http://www.kepital.com/>

Primary contact and correspondent:

Name: Charles Mack

Address: 12226 Washington Lane, Parker, Arizona 85344

Phone” 931-625-4938

Email: charliemack@irc-us.com

2. Device :

Trade/proprietary name : Smiletone®

Common Name : Denture base resin

Classification Name : Resin, Denture, Relining, Repairing, Rebasing

3. Predicate Device :

Manufacturer : Vertex Dental B.V.

Device : ThermoSens Rigid

510(k) Number : K123220 (Decision Date - Dec. 3. 2010)

Manufacturer : Thermoplastic Comfort Systems, Inc.
Device : TCS® Unbreakable
510(k) Number : K053060 (Decision Date - Jul. 20. 2006)

4. Classifications Names & Citations :

21CFR872.3760, EBI, Resin, Denture, Relining, Repairing, Rebasing, Class2

5. Description :

Smiletone® is a thermoplastic material to be used for removable full or partial dental prosthesis. The product is based on a compounded mixture of Polyamide and pigments. Smiletone® is classified as 'Type 3-thermoplastic blank or powder' by EN ISO 20795-1[2013].

The expiry date (use-by date) is for 5 years from the date of manufacture.

6. Indication for use :

Smiletone® (denture base resin) is a thermoplastic resin that is intended to be used in fabrication of removable full and partial dental prosthesis, as well as occlusal splints and night guards. The product is based on a compounded mixture of Polyamide and pigments.

7. Comparison with predicate device :

KOREA ENGINEERING PLASTICS Co., Ltd., believes that the Smiletone® is substantially equivalent to the ThermoSens Rigid of Vertex Dental B.V. and TCS® Unbreakable of Thermoplastic Comfort Systems, Inc..

The Smiletone® described in this 510(k) has the same intended use and similar technical characteristics as the ThermoSens Rigid of Vertex Dental B.V. and TCS® Unbreakable of Thermoplastic Comfort Systems, Inc..

	Vertex (ThermoSens Rigid) Primary Predicate	Thermoplastic Comfort Systems, Inc. Reference Predicate	KOREA ENGINEERING PLASTICS (Smiltone)
510(k) No	K123220	K053060	-
Intended use	Vertex ThermoSens Rigid is intended for removable full and partial dentures as well as splints, telescope constructions and temporary crown and bridge constructions.	Fabrication and repair of removable dental prosthetic devices, such as full and partial dentures, orthodontic devices, occlusal splints, and night guards.	Smilestone® is a thermoplastic resin that is intended to be used in fabrication of removable full and partial dental prosthesis, as well as occlusal splints and night guards.
Biocompatibility	EN ISO 10993-3, 5, 10, 11	EN ISO 10993-3, 5, 10, 11	EN ISO 10993-3, 5, 10, 11
Device description	Vertex ThermoSens Rigid is a thermoplastic material that is intended to be used in the fabrication of removable full and partial dental prostheses. The product is based on a compounded mixture of Polyamide and pigments.	TCS® Unbreakable is a break resistant material used in the fabrication and repair of base plates for removable dental prosthetic appliances where superior flexibility and patient comfort for the lifetime of the prosthetic are significant concerns. This includes, but not to be limited to, full and partial dentures, orthodontic devices, occlusal splints, and night guards.	Smilestone® is a thermoplastic resin that is intended to be used in the fabrication of removable full and partial dental prostheses. The product is based on a compounded mixture of Polyamide and pigments.
Composition of Materials	Polyamide 12	Polyamide 12	Polyamide 12
Physical Properties	Flexural strength : Not tested by Sponsor Impact Strength : 8.0 ± 7.0 kJ/m ² Flexural modulus : 1339 ± 54 MPa Water absorption : 31.2 ± 0.8 μg/mm ³ Water solubility : -0.20 ± 0.25 μg/mm ³	Flexural strength : Not tested by Sponsor Impact Strength : 8.5 ± 1.2 kJ/m ² Flexural modulus : 353 ± 4.24 MPa Water absorption : 14.6 ± 0.4 μg/mm ³ Water solubility : 2.5 ± 0.7 μg/mm ³	Flexural strength : 68 ± 2 MPa Flexural modulus : 1389 ± 35 MPa Water absorption : 30.7 ± 0.2 μg/mm ³ Water solubility : 0.33 ± 0.1 μg/mm ³
Standards of Conformity	ISO 20795-1	EN ISO 20795-1	EN ISO 20795-1

8. Biocompatibility and Performance Data :

Biocompatibility and performance testing according to standard ISO 10993 Series and ISO 20795-1 were performed. All test results were satisfactory.

Title	Test Standard	Results
Dentistry - Medical devices for dentistry – Materials testing	EN 1641(2010)	Pass
Accelerate aging test	ASTM F1980(2002)	Pass
Visual Inspection	Performance test Guidance of dental materials (KFDA 2014)	Pass
Capacity test	Performance test Guidance of dental materials (KFDA 2014)	Pass
Packaging(Visual Inspection) test	Performance test Guidance of dental materials (KFDA 2014)	Pass
Surface characteristics test	EN ISO 20795-1	Pass
Shape characteristics test	EN ISO 20795-1	Pass
Color test	EN ISO 20795-1	Pass
Color Stability test	EN ISO 20795-1	Pass
Translucency test	EN ISO 20795-1	Pass
Freedom from porosity test	EN ISO 20795-1	Pass
Bonding to synthetic polymer teeth test	EN ISO 20795-1	Pass
Residual Monomer test	EN ISO 20795-1	Pass
Sorption test	EN ISO 20795-1	Pass
Solubility test	EN ISO 20795-1	Pass
Ultimate flexural strength test	EN ISO 20795-1	Pass

Title	Test Standard	Results
Genotoxicity test : BACTERIAL REVERSE MUTATION STUDY (AMES)	Under the conditions of ISO 10993-3, Tests for genotoxicity carcinogenicity and reproductive toxicity & OECD 471 Bacterial Reverse Mutation Test, the test articles should meet the test requirements.	Pass
Cytotoxicity Test (Agar diffusion test)	Under the conditions of ISO7405:2008, Evaluation of biocompatibility of medical devices used in dentistry, 6.2 Agar diffusion test, the test articles should meet the test requirements.	Pass
Acute Systemic Toxicity Test	Under the conditions of ISO 10993-11, 5. Acute Systemic Toxicity Test, the test articles should meet the test requirements.	Pass
Maximization Sensitization Test (LLNA-BrdU)	Under the conditions of ISO 10993-10, 7.2. Murine Local Lymph Node Assay (LLNA) & OECD 442B :2010, Skin Sensitization Local Lymph Node Assay : BrdU-ELISA, the test articles should meet the test requirements.	Pass
Oral mucosa irritation test	Under the conditions of ISO10993-10 : 2010, Test for Irritation and skin sensitization Annex B. Special irritation tests B.3 Oral mucosa irritation test, the test articles should meet the test requirements.	Pass

9. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification KOREA ENGINEERING PLASTICS Co., Ltd. concludes that The Smiletone® is substantially equivalent to predicate devices as described herein with reference to biocompatibility, Indications for use and performance data.

10. KOREA ENGINEERING PLASTICS Co., Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END
