

JUN 19 2014



HRS Co.,Ltd.

510(k) SUMMARY

Submitter: HRS CO., LTD.
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 pyongtaek, KOREA, REPUBLIC OF 451-805
 Phone No.: +82-31-655-8822
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 Official Correspondent: Choi, Jae-Hyuen

Date Summary Prepared: OCT 2013

Trade Name: Sildent
 Common Name: Dental Impression Material
 Classification Name: Dental Impression Material(21 CFR § 872.3660)
 Product Code: ELW

Devices for which substantial equivalence is claimed:

Device Name	FLEXTIME	IMPRINT VINYL POLYSILOXANE IMPRESSION MATERIAL
510(k) Number	K000629	K882690

Device Description

The Sildent is a vinyl polysiloxane silicone impression material used for all inlay, crown and bridge, edentulous and partial impressions.

The Sildent consists of 4 type models. These are Sildent light body, Sildent regular body, Sildent heavy body and Sildent putty.



Indications for Use

The Sildent is a vinyl polysiloxane silicone impression material used for all inlay, crown and bridge, edentulous and partial impressions.

Summary of Technological Characteristics Compared to Predicate

	Our Device				Flexitime				3M ESPE			
	Sildent Light	Sildent Regular	Sildent Heavy	Sildent Putty	Light Flow	Mono phase	Heavy Tray	Easy Putty	Light Body	Regular Body	Heavy Body	STD putty
510(k) Number	N/A				K000629				K882690			
Intended Use	The Sildent is a vinyl polysiloxane silicone impression material used for all inlay, crown and bridge, edentulous and partial impressions.				Identical				Identical			
Material	Additional Polyvinyl Silicone Impression Material				Additional Polyvinyl Silicone Impression Material				Additional Polyvinyl Silicone Impression Material			
Form	Cartridge, Putty				Cartridge, Putty				Cartridge, Putty			
Standard	ISO 4823				Identical				Identical			
Sterility	Non sterile				Non sterile				Non sterile			

Non-clinical Performance Data

Biocompatibility study was completed, which demonstrates that the material is safe for its intended use. Sildent was tested through the following tests: Cytotoxicity(Agar Diffusion Test), Short term systemic toxicity(Oral), Oral mucosa irritation, Sensitization.

The 510(k) submission also includes data from bench testing used to evaluate performance characteristics of Sildent as compare to the predicate devices. The characteristics evaluated Dimensional Change, Elastic Recovery, Strain-in Compression, Working Time, Consistency and Mixing Time.



Clinical Testing

Clinical testing has not been conducted on this product.

Conclusions

Non clinical performance testing demonstrates that Sildent is as safe and as effective as the predicate devices.



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

June 19, 2014

HRS Company Limited
Jae-Hyuen Choi
Correspondent
Block 6 choopal industrial complex 394-1 choopal-ri
Pyongtaek,
KOREA, 451-805

Re: K132869
Trade/Device Name: Sildent
Regulation Number: 21 CFR 872.3660
Regulation Name: Dental Impression Material
Regulatory Class: II
Product Code: ELW
Dated: May 19, 2014
Received: May 21, 2014

Dear Mr. 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 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" (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 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,

Mary S. Bunner -S


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): K132869

Device Name: Sildent

Indications for Use:

The Sildent is a vinyl polysiloxane silicone impression material used for all inlay, crown and bridge, edentulous and partial impressions.

Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green, S
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