March 10, 2022

Spident Co., Ltd.
J.M. Ahn
President
203 & 312, Korea Industrial Complex, 722
Gojan-Dong, Namdong-Gu, Incheon 405-821
Korea, South

Re: K214071
Trade/Device Name: Hexa-Temp
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown And Bridge Resin
Regulatory Class: Class II
Product Code: EBG
Dated: December 21, 2021
Received: December 27, 2021

Dear J.M. Ahn:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K214071

Device Name
Hexa-Temp

Indications for Use *(Describe)*
Self-curing temporary crown resin that is used temporarily before repairing a permanent restoration

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5. 510(k) Summary

K214071

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

Date: December 21, 2021

1. Company and Correspondent making the submission:
   Company Name : SPIDENT CO., LTD.
   Address : 203 & 312, Korea Industrial Complex, 722, Gojan-Dong, Namdong-Gu, Incheon, Korea, 405-821
   Tel : +82-32-821-0071
   Fax : + 82-32-821-0074
   Company Contact : J.M. Ahn / President

2. Device Name and Classification
Proprietary Name : **Hexa-Temp**
Common name : Temporary crown and bridge resin
Classification name : Temporary crown and bridge resin [CFR 872.3770]
Product code : EBG
Class : II

3. Predicate Devices (Legally Marketed Devices)

The predicate devices for Hexa-Temp is :

- **STRUCTUR 2 SC,** VOCO GMBH, K040769

4. Description:
Hexa-Temp is temporary crown and bridge resin that is used temporarily before repairing a permanent restoration. It can be self-cured resin. Filler size ranges from 0.7 to 1.2 μm, resulting in good radio-opacity and high flexural strength. Various shades of TW, A1, A2, A3, B1, C2, AO3 and BL for esthetic crown are provided. Hexa-Temp contains about 38% inorganic filler. Inorganic filler has a size of 16nm ~ 3.22μm.

5. Indications for Use
Self-curing temporary crown resin that is used temporarily before repairing a permanent restoration

6. Performance Testing - Bench

The performance test was conducted to prove the substantially equivalence of the subject device, and the standards applied to the performance test are as follows.

- ISO 10477:2018, Dentistry — Polymer-based crown and veneering materials.

7. Biocompatibility

Biocompatibility tests and biological safety evaluation were performed and the results proved that the subject device is at least as biocompatible and biologically safe as the predicate device.

The standards applied are as follows.

- ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-3:2014, Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-6:2016, Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
- ISO 10993-10:2010, Biological evaluation of medical devices. Tests for irritation and skin sensitization
- ISO 10993-11:2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 10993-18:2020, Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process
- ISO 7405:2018, Dentistry – Evaluation of biocompatibility of medical devices used in dentistry

8. Substantial Equivalence Discussion

Product Name	Hexa-Temp	Structur 2 SC
510(k)	N/A	K040769
Manufacturer	SPIDENT CO., LTD.	VOCO GMBH

Product description	Hexa-Temp is temporary crown and bridge resin that is used temporarily before repairing a permanent restoration. It can be self-cured resin. Filler size ranges from 0.7 to 1.2 μm, resulting in good radio-opacity and high flexural strength. Various shades of TW, A1, A2, A3, B1, C2, AO3 and BL for esthetic crown are provided. Hexa-Temp contains about 38% inorganic filler. Inorganic filler has a size of 16nm ~ 3.22μm.	Structur 2 SC is a fluorescent self-curing paste-paste system for the production of temporary crowns, bridges, inlays and onlays. Structur 2 SC consists of base paste and catalyst paste.
Chemical composition of Resin	Methacrylate matrix(Bis-GMA, TEGDMA)	Methacrylates, amines, terpenes, benzoyl peroxide and BHT
Indications for use	Self-curing temporary crown resin that is used temporarily before repairing a permanent restoration	Structur 2SC is indicated for the fabrication of temporary crowns, bridges, inlays and onlays.
Principle of operation	Self-cured	Self-cured
Mechanical Properties •Water sorption ($\mu g/mm^3$)	24.89	14.59
•Solubility ($\mu g/mm^3$)	3.85	3.15
•Color and color consistency	There is Color consistency and Color stability.	There is Color consistency and Color stability.
•Polymerization Temperature	Did not exceed 45°C	Did not exceed 45°C
•Polymerization Shrinkage (%)	2.63	2.50
•Compressive Strength (MPa)	330.38	294.82
•Flexural Strength (MPa)	69.93	86.42

•Surface finish	It's smooth and glossy.	It's smooth and glossy.
Standard conformed	ISO 10477	ISO 10477
Biocompatibility	Yes	Yes
Application Area	Tooth	Tooth
Target Population	Dental patient	Dental patient
Intended Operator	Dentist	Dentist
Storage condition	2-27℃	4-23℃
Shade	TW, A1, A2, A3, B1, C2, AO3 and BL	A1, A2, A3, A3.5, B1, B3, C2 and BL

9. Similarities and Differences with Marketed Devices:

The subject device, Hexa-Temp and the predicate device, Structur 2 SC was compared as above. Both products have the similar product description as a temporary crown and bridge resin.

In case of composition, two products contain slightly different raw materials, but the subject device and the predicate device show the same performance as methacrylic monomer and inhibitor, initiator, pigment, filler. Filler information of predicate device is unknown, but it will be similar as the general characteristics of the temporary crown and bridge resin.

Indication for use of the two products are almost same and both products can be used as self-cure.

As the mechanical properties, clinically important items of the temporary crown resin were selected: Water sorption, Solubility, Color and Color stability, Polymerization temperature, Polymerization shrinkage, Compressive strength, and Flexural strength. Among them, Water sorption, Solubility, Color and Color stability, and Flexural strength belong to ISO 10477 items.

The performance results of the two products are not the same, but both products meet the requirements of ISO 10477 and it can be seen that the main clinical performance is comparable or superior.

For this reason, despite difference in material, both the subject device and the equivalent device have no problem in terms of the clinical performance.

Biocompatibility, Application Area, Target Population, Intended Operator of both products are the same.

In case of Storage condition and Shade, there is a slight difference but performance and biocompatibility test showed that these differences would not raise any new questions of safety and effectiveness. Therefore, Hexa-Temp is substantially equivalent with predicate device, Structur 2 SC, and at least as safe and effective as the predicate device.

10. Conclusion

Based on a comparison of subject device, Hexa-Temp (SPIDENT CO., LTD) and predicate device, Structur 2 SC (VOCO GMBH), it is confirmed that the subject device is substantially equivalent to predicate device.