October 28, 2022

SDI Limited
Quynh Jewell
Regulatory Affairs Manager
3-15 Brunsdon Street, Bayswater
Melbourne, Victoria 3153
Australia

Re: K222583
Trade/Device Name: Stela Capsule System
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF, KLE
Dated: August 26, 2022
Received: August 26, 2022

Dear Quynh Jewell:

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)*
K222583

Device Name
Stela Capsule System

Indications for Use *(Describe)*
Stela Primer:
- Dentin and enamel bonding

Stela Capsule
- Direct Class I, II, III and V cavities. Ideally Class I and II
- Base or liner
- Core build-ups.

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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SDI Limited	**Establishment Registration No:** 3004140838
	PIN: MD6132520
510(k) NOTIFICATION (Traditional): Stela Capsule System – Summary – August 2022	

K222583

1. Submitter Information

SDI Limited
3-15 Brunsdon Street
Bayswater, Victoria 3153
Australia

Contact Person: Quynh Jewell
Position: Regulatory Affairs Manager
Company: SDI Limited
Phone: +61 3 8727 7111
Email: Quynh.Jewell@@sdi.com.au

Date Prepared: 9 September 2022

2. Device Details

The Stela Capsule System comprises the following components:

Proprietary Name:	Stela Capsule
Common Name:	Dental restorative material
Regulation Name:	Tooth shade resin material
Regulation Number:	872.3690
Product Code:	EBF
Regulatory Class:	II

Proprietary Name:	Stela Primer
Common Name:	Dental adhesive
Regulation Name:	Resin tooth bonding agent
Regulation Number:	872.3200
Product Code:	KLE
Regulatory Class:	II

Proprietary Name:	Application brush
Common Name:	Application brush
Regulation Name:	Resin applicator
Regulation Number:	872.3140
Product Code:	KXR
Regulatory Class:	I

Proprietary Name:	SDI Applicator
Common Name:	Applicator/Dispenser
Regulation Name:	Dental hand instruments
Regulation Number:	872.4565
Product Code:	DZN
Regulatory Class:	I

3. Predicate Device

Submitter's Device	**Primary Predicate Device**	**Secondary Predicate Device**
Stela Primer	Name: ParaBond[1] Manufacturer: Coltene 510(k) Number: K053040	Name: Scotchbond Universal Adhesive[2] Manufacturer: 3M ESPE 510(k) Number: K110302
Stela Capsule	Name: Fill-Up! Manufacturer: Coltene 510(k) Number: K150218	Name: Filtek Supreme Ultra Universal Restorative Manufacturer: 3M ESPE 510(k) Number: K083610

[1] ParaBond was originally cleared in ParaCem Universal DC 510(k) based on the National Library of Medicine GUDID database noting ParaBond's 510(k) number as K053040.

[2] Scotchbond Universal Adhesive was originally cleared as Adhesive EXL 759

No reference devices were used in this submission.

It is noted the application brush is exempt from the premarket notification procedure under Regulation 872.3140. The applicator is exempt from the 510(k) procedure under Regulation 872.4565

4. Device Description

The Stela Capsule System is an easy to use bulk-fill radiopaque self-cure dental restorative system for dental professional use. The system comprises:

- Stela Capsule – a capsule consisting of powder and liquid components which are mixed and activated when the capsule is pushed down. After mixing with a triturator (amalgamator) an applicator is used to dispense the paste.
- Stela Primer – an adhesive liquid packaged in a bottle. A bendable disposable brush applicator is used to apply Stela Primer.

The combination of Stela Primer and Stela Capsule will bond to both enamel and dentin without scrubbing or light curing.

5. Indications of Use

The indications for each component of the Stela Capsule System are below.

Stela Primer	Stela Capsule
1) Dentin and enamel bonding	1) Direct restoration of Class I, II, III and V cavities. Ideally Class I and II, 2) Base or liner, 3) Core build-ups

For Stela Primer, the indications are identical to the primary predicate. In comparison to the secondary predicate, Stela Primer's indications are phrased in a broad sense whereas the predicate specifies each use. This difference in wording is not expected to alter the intended use nor affect the safety or effectiveness of Stela Primer compared to the secondary

For Stela Capsule, the indications are nearly identical to the primary predicate with the exception of the direct restoration of Class III and IV cavities which are indicated by the secondary predicate according to its Instructions for Use.

6. Comparison of Technological Characteristics with the Predicate Device

The Stela Capsule System is based on well-established existing self-cure resin technology. The System's two components consist of a 1) combined primer plus bonding agent (Stela Primer) and 2) restorative bulk-fill resin-based material (Stela Capsule).

Stela Primer binds to tooth structure through ionic bonds. Bonding of Stela Primer to Stela Capsule occurs *in situ* upon contact via polymerisation.

At a high level, the Stela Capsule System has the same technological characteristics as the predicate devices. Where differences exist these are as follows:

- Stela Primer number of steps
    - Similar to Scotchbond Universal Adhesive in that it consists of one bottle containing the necessary elements to prime and bond; whereas ParaBond consists of three bottles: a conditioner, adhesive A and adhesive B.
- Stela Primer curing
    - Self-cure like ParaBond; whereas Scotchbond Universal Adhesive is light cured.
- Stela Capsule material and curing
    - radiopaque bulk-fill composite like both predicates. Stela Capsule is self-curing while Fill-Up and Filtek Supreme Ultra Universal Restorative are dual-cure and light-cure, respectively.

7. Performance Data

Biocompatibility testing

The Stela Capsule System is considered an external communicating device in long term contact with tissue/bone/dentin. A biological risk assessment and testing were conducted to assess the biocompatibility of the Stela Capsule System:

- Cytotoxicity tests (ISO 7405:2018, ISO 10993-5:2009)
- Delayed-type hypersensitivity (ISO 10993-10:2010)
- Irritation/intracutaneous reactivity (ISO 10993-10:2010)
- Systemic toxicity (ISO 10993-11:2017)
- Genotoxicity (ISO 10993-3:2014).

The results of the biocompatibility testing and risk assessment demonstrates a low potential for an unacceptable adverse biological response from contact of the component materials of the device with the body.

Non-clinical performance data

Bench testing was conducted to determine the performance of the Stela Capsule System compared to the primary and secondary predicate devices. Testing was conducted on the system where Stela Primer was used in conjunction with Stela Capsule and compared to the equivalent system for the primary and/or secondary predicate device(s). The tests performed were:

- Working time (ISO 4049)
- Setting time (ISO 4049)
- Flexural strength (ISO 4049)
- Shade (ISO 4049)
- Colour stability (ISO 4049)
- Radio-opacity (ISO 4049)
- Shear bond strength to dentin (ISO 29022:2013)
- Shear bond strength to enamel (ISO 29022:2013).

Bench testing demonstrated the Stela Capsule System met the relevant ISO standard requirement, where applicable, and performed comparably to the predicate devices for the parameters tested.

Clinical performance data

This section is not applicable.

Electrical safety and electromagnetic compatibility (EMC)

This section is not applicable.

Software verification and validation testing

This section is not applicable.

Mechanical and acoustic testing

This section is not applicable.

8. Conclusion Regarding Substantial Equivalence

A suite of bench and biocompatibility tests shows Stela Capsule System performs comparably to the predicate devices (when used on a system basis) and possesses a low likelihood of an unacceptable adverse biological response from contact of the component materials of the device with the body. The Stela Capsule System's indications for use are identical or very similar to the predicate devices and they are all based on the same restorative materials technology. On this basis, the Stela Capsule System is substantially equivalent to the predicate devices.