December 2, 2019

SDI Limited
Ray Cahill
Chief Quality and Compliance Officer
3-15 Brunsdon Street
Bayswater, 3153 AU

Re: K191656
Trade/Device Name: Zipbond™
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: September 2, 2019
Received: September 4, 2019

Dear Ray Cahill:

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 Srinivas Nandkumar, Ph.D.
Acting Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191656

Device Name

ZIPBOND™

Indications for Use *(Describe)*

Direct Applications:

- Light cured composite restorations
- Light cured compomers
- Cavity sealing prior to placement of indirect restorations
- Composite repair of porcelain and hybrid ceramic restorations
- Sealing exposed root surfaces which are causing hypersensitivity
- Core build ups using light cure/dual cure composites
- Protective varnish for glass ionomer (GI) filling

Indirect Applications:

- Cementation indirect restorations

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

For

Zipbond™

1. Submitter Information:

SDI Limited
3-15 Brunsdon Street
Bayswater
Victoria 3153
Australia

Contact Person: Ray Cahill
Phone: +61 3 8727 7111
Fax: +61 3 8727 7222
Email: ray.cahill@sdi.com.au

Date Prepared: 26 November 2019

2. Device Details

Proprietary Name: Zipbond™
Common name: Dental bonding agent
Regulation Name: Resin tooth bonding agent
Regulation Number: 21 CFR 872.3200
Product Code: KLE
Regulatory Class: II

3. Predicate device:

Predicate Device name	510(k)	Company name
Scotchbond Universal Adhesive (named as Adhesive EXL 759 in 510k)	K110302	3M Espe AG

4. Device Description:

Zipbond is a single-component, (meth)acrylate-based material which functions as a combined etch-and-rinse (total-etch), self-etch and selective-etch dental adhesive. It offers an adhesive application technique for both direct and indirect indications and bonds to enamel, dentin, composites, cements.

When used with a LED light curing device, Zipbond can be used with self-cure, dual-cure and light cure resin cements, composites and core-build up materials.
Zipbond provides the operator with three choices of enamel and dentin pre-treatment:

- Self-etch mode: no phosphoric acid etching required prior to application

- Selective-etch mode: selective phosphoric acid etching to enamel
- Total-etch mode: phosphoric acid etching of both enamel and dentin

5. Indications of use:

Direct Applications
• Light cured composite restorations
• Light cured compomers
• Cavity sealing prior to placement of indirect restorations
• Composite repair of porcelain and hybrid ceramic restorations
• Sealing exposed root surfaces which are causing hypersensitivity
• Core build ups using light cure/dual cure composites
• Protective varnish for glass ionomer (GI) filling

Indirect Applications
• Cementation indirect restorations

6. Substantial equivalence:

Technical characteristics:

Proposed device: Zipbond, 510K - K191656	**Predicate device: Scotchbond Universal (named as Adhesive EXL 759, in 510K - K110302)**	
Regulation number:	**Regulation number:**	**Differences:**
21 CFR 872.3200	21 CFR 872.3200	No differences
Product code:	**Product code:**	**Differences:**
KLE	KLE	No differences
Regulatory class:	**Regulatory class:**	**Differences:**
II	II	No differences
Regulation name:	**Regulation name:**	**Differences:**
Resin tooth bonding agent	Resin tooth bonding agent	No differences
Common name:	**Common name:**	**Differences:**
Dental bonding agent	Dental bonding agent	No differences
Intended use:	**Intended use:**	**Differences:**
Universal dental adhesive	Universal dental adhesive	No differences
Composition:	**Composition:**	**Differences:**
Functional monomers (methacrylates), photoinitiators, stabilisers, silica, ethanol, water, sodium fluoride	Functional monomers (methacrylates), photoinitiators, stabilisers, silica, ethanol, water	Minor – Zipbond Universal Adhesive contains sodium fluoride. Scotchbond Universal does not mention in their Instructions of Use that it contains fluoride.
Application:	**Application:**	**Differences:**
Liquid	Liquid	No differences
Rx / OTC:	**Rx / OTC:**	**Differences:**
Rx	Rx	No differences
Indications for Use statement:	**Indications for Use statement:**	**Differences:**

Direct Applications: • Light cured composite restorations • Light cured compomers • Cavity sealing prior to placement of indirect restorations • Composite repair of porcelain and hybrid ceramic restorations • Sealing exposed root surfaces which are causing hypersensitivity • Core build ups using light cure/dual cure composites • Protective varnish for glass ionomer (GI) filling Indirect Applications: • Cementation indirect restorations	• All classes of fillings (according to Black) with light-curing composite or compomer filling materials • Cementation of indirect restorations when combined with RelyX Ultimate Adhesive Resin Cement, manufactured by 3M ESPE • Cementation of veneers when combined with RelyX Veneer Cement, manufactured by 3M ESPE • Bonding of core build-ups made of light-curing composite or core build-up materials • Bonding of dual-cure cements and core build-up materials and self-cure composites when combined with Scotchbond Universal DCA • Repair of composite or compomer fillings • Intraoral repair of composite restorations, porcelain fused to metal, and all-ceramic restorations without extra primer • Root surface desensitization • Sealing of cavities prior to cementation of amalgam restorations • Sealing of cavities and preparation of tooth stumps prior to temporary cementation of indirect restorations • Bonding of fissure sealants • Protective varnish for glass ionomer fillings	Minor – Zipbond is not used with a dual-cure activator, and requires light curing before placement of dual-cure cements, core build up materials and self-cure composites.
Indications for Use:	**Indications for Use:**	**Differences:**
Light cured composite restorations	All classes of fillings (according to Black) with light-curing composite or compomer filling materials Cementation of veneers when combined with RelyX Veneer Cement, manufactured by 3M ESPE	No differences – classes of fillings according to Black include direct restorations
Light cured compomers		

Cavity sealing prior to placement of indirect restorations	Sealing of cavities prior to cementation of amalgam restorations	No differences – sealing of cavities prior to placement of indirect restorations
	Sealing of cavities and preparation of tooth stumps prior to temporary cementation of indirect restorations	
Composite repair of porcelain and hybrid ceramic restorations	Intraoral repair of composite restorations, porcelain fused to metal, and all-ceramic restorations without extra primer Repair of composite or compomer fillings	No differences– Zipbond hybrid ceramic restorations include porcelain fused to metal.
Sealing exposed root surfaces which are causing hypersensitivity	Root surface desensitization	No differences – sealing root surfaces results in desensitization
Core build ups using light cure/dual cure composites	Bonding of core build-ups made of light-curing composite or core build-up materials	Minor indication – predicate device Scotchbond Universal is used with a dual cure activator when bonding with dual-cure cements, core build-up materials and self-cure composites, whereas subject device Zipbond is not used with a dual cure activator and is to be prior light cured when bonding to these materials.
	Bonding of dual-cure cements and core build-up materials and self-cure composites when combined with Scotchbond Universal DCA	
Protective varnish for glass ionomer (GI) filling	Protective varnish for glass ionomer fillings	No differences
Cementation indirect restorations	Cementation of indirect restorations when combined with RelyX Ultimate Adhesive Resin Cement, manufactured by 3M ESPE	No differences – predicate device Scotchbond Universal indication describes the compatibility of the dental adhesive with a specific resin cement, RelyX Ultimate Adhesive Resin Cement. The adhesive bonds the indirect substrate to the prepared tooth cavity. The tooth cavity may incorporate a luting cement, based on the substrate manufacturer's Instructions for Use.
Light cured composite restorations	Bonding of fissure sealants	No differences - fissure is a small dental cavity which

		can be filled by a light-cured composite.
Features:	**Features:**	**Differences:**
Single-component, light curing universal adhesive	Single-component, light curing adhesive	No differences
Self-etch, selective etch (to enamel), or total etch techniques	Self-etch, selective enamel etch, or total etch techniques	No differences
Light-curing universal adhesive No dual-cure activator	Light-curing universal adhesive used without separate Activator for assigned materials (reference cements). Use with separate dual-cure Activator for use with dual-cure cement, core build up materials and self cure composites.	Both are light-curing adhesive systems. Predicate device Scotchbond Universal uses a dual-cure activator when bonding of dual-cure cements and core build-up materials, and self cure composites. Subject device Zipbond does not use a dual-cure activator and requires prior light curing when bonding to dual-cure cements, core build-up materials and self cure composites.

Subject device Zipbond and predicate device Scotchbond Universal share the same technological characteristics – both are composed of functional monomers (methacrylates), photoinitiators, stabilisers, silica, ethanol, water. Zipbond also contains sodium fluoride as a fluoride source. Both devices are light-curing dental adhesives using the self-etch, selective enamel etch, or total etch techniques. Predicate device Scotchbond Universal can be used with a dual-cure activator when bonding to dual-cure cements, core build-up materials, and self cure composites, whereas subject device Zipbond requires prior light curing to bond to these materials. Both devices performed similarly for shear bond strength according to *ISO 29022:2013-Dentistry – Adhesion - Notched-edge Shear Bond Strength Test.*

7.Non-Clinical Performance Data:

The following in-vitro bench tests were performed on Zipbond to verify physical properties and performance in support of substantial equivalence:

- pH measurement according to internal method
- Shear bond strength on enamel and dentin according to *ISO 29022:2013-Dentistry-Adhesion-Notched edge shear bond strength test.*

The performance of Zipbond satisfactorily met the requirements of the non-clinical bench testing conducted to support substantial equivalence.

Biocompatibility testing was conducted according to ISO 10993-1 - *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*, and ISO 7405– *Dentistry – Evaluation of biocompatibility of medical devices used in dentistry*

The results of the biocompatibility testing and biological risk assessment conducted relating to the subject device Zipbond support its substantial equivalence.

8. Conclusion Regarding Substantial Equivalence:

Zipbond has the same intended use, incorporates the same fundamental technology, and has similar indications for use as the predicate device Scotchbond Universal. Test data to verify physical properties and the performance of Zipbond has been provided including: appearance, pH, shear bond strength on various substrates. The results of the testing, combined with the design and indications for use comparison with predicate device Scotchbond Universal support substantial equivalence.