September 22, 2023

Sino-Dentex Co., Ltd.
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K232978
Trade/Device Name: DX. Bond V Dental Bonding Adhesive
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin tooth bonding agent
Regulatory Class: Class II
Product Code: KLE
Dated: September 21, 2023
Received: September 21, 2022

Dear Prithul Bom:

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,

Michael E. Adjodha -S

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.

Submission Number *(if known)*

K232978

Device Name

DX. Bond V Dental Bonding Adhesive (Universal-003, Universal-005)

Indications for Use *(Describe)*

- Bonding for all Classes of direct composite restoration
- Bonding for indirect procedures involving metal, porcelain and composite

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Kxxxxx

510 K SUMMARY

1. SUBMITTER INFORMATION

Applicant Information: SINO-DENTEX CO.,LTD.
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Manufacturer Contact: SINO-DENTEX CO., LTD.
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Tel: (086) 18943173317
Fax: (086) 431-87855157

Summary Preparation Date: 8/25/2023

Type of 510(k) Submission: Traditional 510 (k)

2. DEVICE DETAIL:

Device Classification Name:	Agent, tooth bonding, resin
Device Trade Name:	DX. Bond V Dental Bonding Adhesive
Common Name:	Dental Bonding Adhesive
Model Number:	Universal-003, Universal-005
Regulation Number:	21 CFR 872.3200

Regulation Medical Specialty: Dental
Regulatory Class: Class II
Product Code: KLE

3. LEGALLY MARKETED PREDICATE DEVICE:

Device Classification Name: Agent, tooth bonding, resin
Device Trade Name: Scotchbond Dental Adhesive
Common Name: Dental Bonding Adhesive
Regulation Number: 21 CFR 872.3200
Regulation Medical Specialty: Dental
Regulatory Class: Class II
Product Code: KLE
510 K: K81380
Manufacture: 3M

4. DEVICE DESCRIPTION:

DX. Bond V Dental Bonding Adhesive is a multi-purpose dental bonding adhesive for all classes of direct composite restoration as well as for indirect procedures involving metal, porcelain and composite. DX. Bond V is also used for amalgam, self- cure composite and orthodontic brackets bonding. DX. Bond V consists of methylmethacrylates and solvent. After applied to bonding area with thin layer, methylmethacrylates are initiated by free radical with blue light and then polymerized to form cross-linking polymer network resulting in solid and strong bonding membrane. The adhesive is dropped onto a mixing pad before application.

5. INDICATIONS FOR USE:

1.Bonding for all Classes of direct composite restoration
2.Bonding for indirect procedures involving metal, porcelain, and composite

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCIE:

Both Dentex DX. Bond V Dental Bonding Adhesive and the predicate device 3M Scotchbond Dental Adhesive have similar chemistry composition. Both use

BisGMA, HEMA as main monomer, and Camphorquinone/ Ethyl-4-dimethyl amino benzoate as initiator system. The major difference is solvent and ethylene dimethacrylate monomer. Dentex DX. Bond V Dental Bonding Adhesive utilizes acetone/ethanol as the solvents and the predicate devices only has ethanol in it. Acetone/ethanol combination is more volatile for reduction of any residual solvent on bonding body which may decrease the curability of the adhesive. Both ethanol and acetone are common materials in dental application and evaporated in short time after application. Dentex DX. Bond V Dental Bonding Adhesive is added with Ethylene dimetharylate monomer which has been applied extensively in dental restorative materials for many years. Its major function is to dilute thick BisGMA. So, the difference has not affected the safety and effectiveness of the device.

7. PERFORMANCE DATA

Biocompatibility testing

DX. Bond V Dental Bonding Adhesive is considered a communicating device in long term contact with tissue/bone/dentin. A biological risk assessment and testing were conducted to assess the biocompatibility of the DX. Bond V:

- Cytotoxicity tests (ISO 10993-5:2009)
- Sensitivity Test (ISO 10993-10:2010)
- Irritation Test (ISO 10993-23:2021)
- Acute 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 DX. Bond V compared to the predicate devices. The tests performed were:

- Film thickness: ISO 4049:2010
- Shear bonding: ISO/TS 11405:2015; ISO29022:2013
- Light sensitivity: ISO 4049:2010

- Microleakage: ISO/TS 11405:2015

Bench testing demonstrated the DX. Bond V Dental Bonding Adhesive 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

The conclusions drawn from the bench and biocompatibility tests demonstrate that the proposed subject device is as safe, as effective, and performs as well as the legally marketed predicate device, 3M Scotchbond Dental Adhesive cleared under K813180.