December 22, 2023

3M Unitek Orthodontic Products
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K234043
Trade/Device Name: 3M™ Transbond™ Orthodontic Adhesive
Regulation Number: 21 CFR 872.3750
Regulation Name: Bracket adhesive resin and tooth conditioner
Regulatory Class: Class II
Product Code: DYH
Dated: December 20, 2023
Received: December 21, 2023

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, MChE, RAC, CQIA
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K234043

Device Name

3M™ Transbond™ Orthodontic Adhesive

Indications for Use *(Describe)*

3M Transbond Orthodontic Adhesive is indicated for the following uses:
- Creating attachments for orthodontic tray aligners.
- Bonding orthodontic brackets to teeth.

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

Prepared on: 2023-12-08

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	3M Unitek Orthodontic Products
Applicant Address	2724 SOUTH PECK RD. Monrovia CA 91016 United States
Applicant Contact Telephone	651-467-3014
Applicant Contact	Mr. Chandrapaul Parsram
Applicant Contact Email	cparsram@mmm.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	3M™ Transbond™ Orthodontic Adhesive
Common Name	Bracket adhesive resin and tooth conditioner
Classification Name	Adhesive, Bracket And Tooth Conditioner, Resin
Regulation Number	872.3750
Product Code	DYH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K083051	FlowTain	DYH
K073697	Transbond Supreme LV	DYH
K221695	3M™ Filtek™ Supreme Flowable Restorative	EBF

Device Description Summary

21 CFR 807.92(a)(4)

3M Transbond Orthodontic Adhesive is a thixotropic, visible-light activated, radiopaque orthodontic adhesive. The product is stored in a multi-use syringe which is used with single-use dispensing tips.

3M Transbond Orthodontic Adhesive contains bisGMA, TEGDMA and Procrylat resins. The fillers are a combination of ytterbium trifluoride filler with a range of particles sizes from 0.1 to 5.0 microns, a non-agglomerated/non-aggregated surface modified 20 nm silica filler, a non-agglomerated/non-aggregated surface modified 75 nm silica filler, and a surface modified aggregated zirconia/silica cluster filler (comprised of 20 nm silica and 4 to 11 nm zirconia particles). The aggregate has an average cluster particle size of 0.6 to 10 microns. The inorganic filler loading is approximately 65% by weight (46% by volume).

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

3M Transbond Orthodontic Adhesive is indicated for the following uses:
- Creating attachments for orthodontic tray aligners.
- Bonding orthodontic brackets to teeth.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The intended use of the proposed device and the predicate device, FlowTain (K083051), is the same.

The indications of use of the proposed device is substantially equivalent to the predicate device. Both products are indicated for use in for creating attachments for orthodontic tray aligners as well as bonding orthodontic brackets to the teeth.

Technological Comparison 21 CFR 807.92(a)(6)

The proposed device and the predicate device, FlowTain (K083051), have similar but not identical technological characteristics. Both devices are non-sterile, light-cured, single-paste resin adhesive packaged in a multi-use syringe with single-use needlepoint tips for dispensing.

Characteristics that are not identical between the proposed and predicate devices include curing conditions, nanomaterials, and materials used in the formulation.

Transbond Supreme LV (K073697) and 3M Filtek Supreme Flowable Restorative (K221695) are used as reference devices to demonstrate that the differences in technological characteristics between the proposed and predicate devices do not raise significant concern about safety or effectiveness. Transbond Supreme LV (K073697) and 3M Filtek Supreme Flowable Restorative (K221695) have similar curing conditions and are formulated with similar materials as the proposed device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following performance parameters were tested to demonstrate that the subject device performs as intended when used for creating attachments for orthodontic tray aligners or bonding brackets to teeth: Shear Bond Strength (adhesion), Depth of Cure (ISO 4049), Three-Body Wear Resistance, and Rheology.

FlowTain (predicate device) and/or 3M Transbond Supreme LV (reference device) were used as controls in these studies.

Not Applicable.

The performance bench studies and biocompatibility assessment show that the subject device is as safe, as effective, and performs as well as or better than the predicate and/or reference device.