July 20, 2021

Reliance Orthodontic Products, Inc
% Brian Dean
Biomedical Engineering Consultant
Cook Device Solutions
7640 Delaine Ct
Indianapolis, Indiana 46254

Re: K210349
Trade/Device Name: TKO Composite Bite Turbo Gel
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: June 23, 2021
Received: June 24, 2021

Dear Brian Dean:

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: 0MB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K210349

Device Name
TKO Composite Bite Turbo Gel

Indications for Use *(Describe)*

TKO is a pink, flowable light cure composite gel for the creation of occlusal buildups (bite turbos) and as a retainer repair composite.

Type of Use *(Select one or both, as applicable)*

[X] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

SECTION 5.0 – 510 (k) Summary

Reliance Orthodontic Products Inc. 1540 West Thorndale Ave. Itasca, IL 60143 USA
Phone: (630) 773-4009 | Website: www.relianceorthodontics.com

1. Submitter Information:

Date of 510(k) Summary: 6/23/2021
Submitter: Reliance Orthodontics Products Inc.
Preparer and Contact Name: Brian Dean, BME Consultant Email: bdean@cookds.com
510(k) Owner: Paul Gange, President Email: pgange@relianceorthodontics.com
Address: 1540 West Thorndale Ave. Itasca, IL 60143 USA
Phone: 630-773-4009 / Fax: 630-250-7704

2. Device Name and Classification:

Common Name of Device:	Orthodontic Light Cure Dental Resin
Device Proprietary Name:	TKO Composite Bite Turbo Gel
Classification Panel:	Dental
Classification Number:	872.3690
Classification Name:	Tooth shade resin material
Class:	II
Product Code:	EBF
510(k) Number:	K210349

3. Substantial Equivalence:

Legally marketed devices to with equivalence is claimed:

- Primary predicate: Ortho Bite 510(k) K192682
- Reference: Triad Orthodontic Gel 510(k) K882482

4. Device Description

Intended for use in the creation of occlusal buildups (bite turbos) and as a retainer repair composite. It bonds to enamel, porcelain, acrylic and metal for duration of treatment. It is categorized as a permanent externally communicating device that contacts tissue/bone/dentin.

TKO Composite Bite Turbo Gel is dispensed from a precision 3.5 gm LuerLoc syringe with tips.

5. Indications for Use and Population:

Intended Use: TKO Composite Bite Turbo Gel is intended for use as a flowable light cure composite gel for the creation of occlusal buildups (bite turbos) and as a retainer repair composite.

Diseases/Conditions for diagnosis, treatment, prevention, cure, or mitigation: None

Population: Orthodontic or Dental Office

6. Predicate Devices:

a. Ortho Bite 510(k) K192682 is similar in intended use, handling and technology compared to the device described in this submission.
b. Triad Orthodontic Gel 510(k) K882482 dated 08/12/1988 is similar in intended use, handling and technology compared to the device described in this submission.
c. Comparison of Technological Characteristics with the predicate devices:

RELIANCE ORTHODONTIC PRODUCTS
Reliance Orthodontic Products Inc. 1540 West Thorndale Ave. Itasca, IL 60143 USA
Phone: (630) 773-4009 | Website: www.relianceorthodontics.com

Submission	**Reliance Orthodontics K210349**	**Dentscare Ltda K192682**	**Dentsply International K882482**
Model	TKO Composite Bite Turbo Gel	Ortho Bite™	Triad Orthodontic Gel
Classification	Class II, EBF, 21CFR872.3690	Class II, EBF, 21CFR872.3690	Class II, EBI, 21CFR872.3760
Intended Use	TKO is a pink, flowable light cure composite gel for the creation of occlusal buildups (bite turbos) and as a retainer repair composite.	The product is indicated for cementing orthodontic bands and is also suitable for temporary dental disocclusion during orthodontic treatment.	Triad Gel Material is a visible light cure material indicated for the fabrication of functional orthodontic appliances, repairs, relines and rebases.
Device Description	Intended for use in the creation of occlusal buildups (bite turbos) and as a retainer repair composite. It bonds to enamel, porcelain, acrylic and metal for duration of treatment. It is categorized as a permanent externally communicating device that contacts tissue/bone/dentin.	Ortho Bite is a light-curing self-adhesive composite with self-levelling characteristics and surface hardness. The product is colored in order to facilitate its identification during application and removal.	Triad Gel Material is suitable where materials with high flow characteristics are desired, such as when encapsulating and retaining orthodontic wires, mesh, etc. Triad Gel Material contains no methyl methacrylate monomer.
Chemical Composition	Urethane Dimethacrylate Triethylene Glycol Dimethacrylate Hexafunctional Urethane Acrylate Oligomer 2-Ethyl-4-dimethlaminobenzoate Camphorquinone FD&C Red #40	The adhesives contain methacrylate as resin fillers and silica that is used as fillers. Its composition includes dimethacrylate monomers, HEMA Phosphate, traditional Camphorquinone/DABE system as photoinitiator and silica as load particle. The combination of silica load fillers with the dimethacrylate monomer composition results in a viscosity that allows it to be handled and applied without running off the application area. The presence of HEMA Phosphate allows adhesion to the enamel surface, which is a known feature of composite cements indicated for bracket bonding. The thixotropy allows the product to have self-levelling capability, known as a shear thinning property that makes the composite settle correctly on the occlusal surface.	80-100% Proprietary Aliphatic Urethane Methacrylate 1-10% Amorphous Precipitated Silica

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Submission	Reliance Orthodontics K210349	Dentscare Ltda K192682	Dentsply International K882482
Dispensing	Precision syringe (3.5 gm)	Syringe (4 g)	Squeeze tube (22 gm)
Sterilization	Non-Sterile	Non-Sterile	Non-Sterile
Shelf-Life	24 months at room temperature	36 months at 5° to 27°C	24 months at < 75 °F
Method of Cure	Light cure for 20 seconds from close range with a dental curing light of 1000 mW or more.	Light cure. Data on time to cure not available at time of submission.	Light cure at variable times from 30 sec to 3 minutes per use case.
Color	Pink	Pink Blue Colorless (UV Trace)	Clear, colorless Clear, blue Clear, pink Clear, red

i. Summary of the different technological characteristics of the subject devices compared to the predicate and reference devices

Despite the indications for use statement for TKO being not identical to the predicates in that the predicate device includes additional indication of bonding of tubes and/or bands and wording is slightly different; the differences do not alter the intended use of the device relative to the predicate, since all devices have the same intended use, that is to be used as a bonding agent for orthodontic appliances. Regarding the indication for temporary dental disocclusion during orthodontic treatment, that is an additional and exclusive indication to the predicate device Ortho Bite. The use of these materials is a common method to create mini-bite plane in daily orthodontic practice. The subject device is similar to the predicate devices in that they are all light-curing resin cements to be used for cementation of orthodontic pieces. The subject device and the predicate devices have substantially equivalent indications for use, shelf life, physical, technological and mechanical properties. All products, including the reference device, meet the same recognized standards. The subject devices are slightly different from the predicate and reference devices, in that they contain the same key biocompatible ingredients, but in different proportions. The primary difference between TKO, Triad Gel, and Ortho Bite is the method of dispensation where TKO and Ortho Bite utilize a syringe.

ii. Non-Clinical Data Submitted

TKO Composite Bite Turbo Gel was tested against physical parameter requirements of the Triad Orthodontic Gel by Dentsply International and compared with the Dentscare Ltda Ortho Bite. The following performance data were provided in support of the substantial equivalence determination where all elements were found to be compliant:

Characteristic	Test Method	Unit	Requirement (High Performance / Critical Area)	Test Result
Shear Bond Strength Enamel	RD-022	MPa	5 sample average ≥ 8	**Pass** 16.47 ± 4.24

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Shear Bond Strength Steel	RD-022	MPa	5 sample average ≥ 8	**Pass** 36.157 ± 1.37
Shear Bond Strength Porcelain	RD-022	MPa	5 sample average ≥ 8	**Pass** 21.54 ± 5.12
Shear Bond Strength Acrylic	RD-022	MPa	5 sample average ≥ 8	**Pass** 24.28 ± 3.57
Flexural Strength ISO-4049:2019	ISO-4049:2019	MPa	4 of 5 samples ≥ 80	**Pass** 5 of 5 samples > 80
Hardness after Cure	QC-006	N/mm2	≥ 69 Top ≥ 67 Bottom After 20 s L/C	**Pass** >69 Top > 67 Bottom
Depth of Cure	ISO 4049:2019	mm	3 of 3 samples ≥ 1.5	**Pass** 3 of 3 samples > 1.5
Sensitivity to Ambient Light	ISO 4049:2019	Homogeneous visual inspection	3 of 3 samples	**Pass** 3 of 3 samples homogenous
Water Sorption	ISO 4049:2019	µg/mm3	4 of 5 ≤ 40	**Pass** 5 of 5 < 40
Water Solubility	ISO 4049:2019	µg/mm3	4 of 5 ≤ 7.5	**Pass** 5 of 5 < 7.5
Biocompatibility	ISO 10993-5 ISO 7405:2018	N/A	Passes Cytotoxicity or Oral Toxicity testing	**Pass** 14 day oral toxicity
Storage and Shelf Life	Stability study for 3.7 months at 50 °C	N/A	SBS, Flexural Strength, and Hardness after cure pass after cure	**Pass** 24 month shelf life at room temperature.
Packaging	RD-037	N/A	Passes suitability testing	**Pass**

iii. Conclusions

Clinical testing was determined to be unnecessary with the approval of all non-clinical testing. Based on the nonclinical testing conducted and equivalency in characteristics demonstrated between Reliance TKO, Dentscare Ltda Ortho Bite, and Dentsply International Triad Gel devices. In conjunction with biocompatibility demonstrated via ISO 7405 and ISO 10993-5 evaluations, evidence has been submitted to demonstrate Reliance TKO is substantially equivalent to the predicate device in biocompatibility and equivalent to or better than the predicate devices in terms of performance against its intended use.