August 14, 2020

Dentscare Ltda
℅ Rodrigo Abreu
Regulatory Specialist
United Regulatory LLC
12343 NW 25th St
Coral Springs, Florida 33065

Re: K192682
Trade/Device Name: Orthocem, Ortho Bite
Regulation Number: 21 CFR 872.3750
Regulation Name: Bracket Adhesive Resin And Tooth Conditioner
Regulatory Class: Class II
Product Code: DYH, EBF
Dated: July 14, 2020
Received: July 20, 2020

Dear Rodrigo Abreu:

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 “Nandu” Nandkumar, Ph.D.
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)*
K192682

Device Name
Orthocem and Ortho Bite

Indications for Use *(Describe)*

Orthocem
Cementation of metal, ceramic or polycarbonate brackets or tubes to enamel surface.

Ortho bite
The product is indicated for cementing orthodontic bands and is also suitable for temporary dental disocclusion during orthodontic treatment.

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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AV. EDGAR NELSON MEISTER, 474, JOINVILLE,
SANTA CATARINA 89219-501 BRAZIL
Ph: 55 - 47 – 3441-6131

510(k) SUMMARY

A) Submitter's Name: DENTSCARE LTDA

Owner / Operator Registration Number: 3007210751

Manufacture Registration Number: 3007210751

B) Address: AV. EDGAR NELSON MEISTER, 474, JOINVILLE, SANTA CATARINA 89219-501 BRAZIL

C) Phone and Fax Numbers

Phone: +55 (47) 34416131

D) Contact Person:

Roberta Uyara

Tel.: +55 (47) 34416131

Email: roberta.uyara@fgm.ind.br

E) Most Recent Revision Date: August 12, 2020

F) Classification Name: Bracket adhesive resin and tooth conditioner

Common / Usual Name: Bracket adhesive resin and tooth conditioner

Proprietary Name: Orthocem and Ortho Bite

Product Code: DYH and EBF

Class: Class II

Regulation: 21 CFR 872.3750

G) Device Description

Orthocem

Orthocem is a light-curing orthodontic single syringe cement that promotes the union between ceramics or metal brackets to the enamel surface. It has a fluorescent substance that allows tracing the product when applying ultraviolet light, facilitating product´s removal from teeth, after removing brackets.

Ortho Bite

Ortho Bite is a light-curing self-adhesive composite with self-levelling characteristics and surface hardness. 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

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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. The product is colored in order to facilitate its identification during application and removal.

H) Substantial Equivalence:

The Orthocem and Ortho Bite are equivalent with the following products:

510(k) Number	Model	Company
K880393 (primary predicate)	Transbond™ XT	3M Unitek

I) Secondary Predicate:

510(k) Number	Model	Company
K924151	Bisco D/C Resinomer (Ultra Band-Lok)	BISCO, INC. (Reliance Orthodontic Products, Inc. as Repackager/Relabeler; Specification Developer)

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J) Indication for Use:

Indication for Use Comparison		
Orthocem and Ortho Bite	**Transbond™ XT**	**Bisco D/C Resinomer (Ultra Band-Lok)**
Orthocem Cementation of metal, ceramic or polycarbonate brackets or tubes to enamel surface. **Ortho bite** The product is indicated for cementing orthodontic bands and is also suitable for temporary dental disocclusion during orthodontic treatment.	Intended for direct bonding of ceramic brackets and metal brackets.	Ultra Band-Lok® is intended for use as an orthodontic band cement and for occlusal buildups.

K) Technological Characteristics Comparison:

The predicate and reference devices used to establish substantial equivalence for the Orthocem and Ortho Bite device are outlined below. This section of this submission will provide a comparison of design, materials, and technical specifications of the Orthocem and Ortho Bite to each of the predicate devices stratified by functional modality.

Device Manufacturer and Common Name	**Orthocem and Ortho Bite** DentsCare	**Transbond™ XT** 3M Unitek	**Ultra Band-Lok (Bisco D/C Resinomer)** Reliance Orthodontic Products, Inc.
510k #	K192682	K880393	K924151
Classification	Class II	Class II	Class II
Regulation #	21 CFR 872.3750	21 CFR 872.3750	21 CFR 872.3690
Product Code	DYH, EBF	DYH	EBF
Classification Name	Bracket adhesive resin and tooth conditioner Tooth shade resin material	Bracket adhesive resin and tooth conditioner	Tooth shade resin material

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Patient Population	Adults	Adults	Adults
Prescription Use	RX only	RX only	RX only
Environment	Dental prosthetics and authorized laboratories and clinics. Orthocem must be stored in temperatures between 5° to 30°C. Ortho Bite must be stored in temperatures between 5° to 27°C.	Dental prosthetics and authorized laboratories and clinics. Transbond™ XT must be stored in temperatures between 2° to 27°C.	Dental prosthetics and authorized laboratories and clinics. Ultra Band-Lok must be stored at room temperature (15-30°C).
Applicable Standards	ISO 4049; ISO 29022; ISO 10993	Not Available, details not disclosed by manufacturer.	Not Available, details not disclosed by manufacturer.
Base Composition	The adhesives contain methacrylate as resin fillers and silica that is used as fillers.	The adhesive contains methacrylate as resin fillers and silica that is used as fillers.	The adhesive contains methacrylate as resin fillers and silica that is used as fillers.
Device Sterilization	Not Applicable	Not Applicable	Not Applicable
Primary Package Container:	Capsule, Syringe	Capsule, Syringe	Syringe
Shelf life	Orthocem: 2 years Ortho Bite: 3 years	Not Available, details not disclosed by manufacturer.	Not Available, details not disclosed by manufacturer.
Use the same materials or substances in contact with the same human tissues or body fluids?	YES	YES	YES
Is the product in compliance to EN ISO 10993?	YES	YES	YES
Tissues	Enamel and Dentin	Enamel and Dentin	Enamel and Dentin

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Reusable	NO	NO	NO
Duration	Permanent	Permanent	Permanent
Part of body	Oral, tooth	Oral, tooth	Oral, tooth
Is it used for the same clinical condition?	YES	YES	YES
Is it used at the same site in the body?	YES	YES	YES
Is it used in a similar population?	YES	YES	YES
Is it used for the same intended purpose?	YES	YES	YES
Is not foreseen to deliver significantly different performances?	NO	NO	NO
Is it similar conditions of use?	YES	YES	YES
Is it similar specifications and properties	YES	YES	YES
Is it similar principles of operation?	YES	YES	YES

	Orthocem	**Ortho Bite**	**Transbond XT**	**Ultra Band-Lok**
Sensitivity to ambient light	Physically homogeneous	Physically homogeneous	Physically homogeneous	Not disclosed by the manufacturer[1]
Depth of cure	2.830 mm	2.993 mm	2.993 mm	Not disclosed by the manufacturer[1]
Flexural strength	82.01 MPa	118.30 MPa	142.30 MPa	Not disclosed by the manufacturer[1]

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Ph: 55 - 47 – 3441-6131

Water sorption and solubility	Sorption: 31.43 µg/mm³ Solubility: 5.66 µg/mm³	Sorption: 30.16 µg/mm³ Solubility: 5.76 µg/mm³	Sorption: 25.13 µg/mm³ Solubility: 5.50 µg/mm³	Not disclosed by the manufacturer[1]
Shear Bond Strength – ISO 29022	14.70 MPa	14.76 MPa	15.44 MPa	Not disclosed by the manufacturer[1]

[1] According to the product code classification, EBF, the product should meet the recognized consensus standards ISO 29022, ISO 10993 and ISO 4049, that are the same normatives considered for Orthocem and Ortho Bite.

Substantial Equivalence Discussion:

Despite the indications for use statement for Orthocem and Ortho Bite are not identical to the predicate in that the subject devices include 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 subject device Ortho Bite, this intended use is similar that of the reference device, Ultra Band-Lok. The use of these materials is a common method to create mini-biteplane in daily orthodontic practice.

The subject devices are similar to the predicate devices in that they are all light-curing resin cements to be used for cementation of orthodontic pieces. The subject devices and the predicate devices have substantially equivalent of indications for use, shelf life, physical, technological and mechanical properties. As depicted above, the value for the flexural strength between the subject devices and predicate device demonstrate higher value for the predicate device. This difference does not affect the substantial equivalence, since all products, including the reference device, meet the same recognized standards. The subject devices are slightly different from the predicate and reference devices, they contain the same key biocompatible ingredients, but in different proportions. The biocompatibility test report supports this difference and it does not affect the substantial equivalence.

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AV. EDGAR NELSON MEISTER, 474, JOINVILLE,
SANTA CATARINA 89219-501 BRAZIL
Ph: 55 - 47 – 3441-6131

L) Applicable Standards:

In order to reach substantially equivalent to the predicate devices the device Orthocem and Ortho Bite was developed, as well produced in compliance with recognized international regulations and standards for the medical device industry.

ISO 4049 - Dentistry - Polymer-based restorative materials

ISO 10993-1 - Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process (ENISO 10993-1:2009)

ISO 29022 - Dentistry -- Adhesion -- Notched-edge shear bond strength test

Conclusion:

Based on compliance with the international standard and regulation mentioned above, the device Orthocem and Ortho Bite demonstrate equivalency to the predicates above.

DENTSCARE LTDA
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SANTA CATARINA 89219-501 BRAZIL
Ph: 55 - 47 – 3441-6131

M) Non-clinical Testing:

In order to study the performance of the product, pre-clinical tests were performed according to the table below, for test results summary please see below.

ORTHOCEM

Test	Specification	Results
Sensitivity to environment lighting – ISO 4049	According to the ISO 4049 standard, acceptance is related to the physical homogeneity of the sample, so the material was compared after the test to the same material pressed between coverslips, but without exposure to ambient light. Thus, there is no difference between the samples.	All results are within the range specified by ISO 4049.
Depth of Cure - ISO 4049	According to ISO 4049, the specification for this material is that its curing depth is: > 1.0 mm for opaque materials and > 1.5 mm for non-opaque materials.	All results are greater than the specified threshold, therefore the material is considered to be in conformity.
Flexural strength	According to the EN ISO 4049 standard the specification for flexural strength is ≥50MPa.	All results are greater than the specified threshold, therefore the material is considered to be in conformity
Water sorption and solubility	Sorption: Maximum of 40 µg/mm³. Solubility: maximum of 7.5 µg/mm³.	The results demonstrate that the product complies the specification in the EN ISO 4049 Standard.
Accelerated Stability Studies	Study created to accelerate the possible chemical degradation and/or physical changes of the product in forced conditions of storage.	Considering the results observed at the end of the 183 days test period, the shelf-life of 2 years in the storage condition of 30°C for the product can be confirmed.
Evaluation Report of Long-Term Stability (Shelf)	Study designed to verify the physical and chemical characteristics of the product during the expected shelf life. The results are used to confirm the expiration date and storage conditions.	Considering the results observed at the end of the 24 months of the long-term test (shelf), the shelf life of 2 years in the storage condition of 30°C for the product can be confirmed.
Transport evaluation report	We performed a testing according to ASTM D4169	The testing results were successful and we had only aesthetic damages considered irrelevant. However, initially the test report advised that the packages did not meet the minimum criteria for compression testing. Therefore, a new testing was performed aiming to re-evaluate the paperboard compression resistance. DENTSCARE modified the paperboard specs and submitted to CETEA to repeat the assessment. According to TEST REPORT CETEA RE 07.217/17, all evaluated samples met the compression criteria required by ASTM D4169 standard.
Shear Bond Strength – ISO 29022	According to ISO 29022 standard, the test verifies the adhesive bond strength between direct dental restorative materials and tooth structure. The results are used to confirm the adhesion of the product to the teeth surface.	Orthocem: 14.70 MPa Ortho Bite: 14.76 MPa Transbond XT: 15.44 MPa

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Ph: 55 - 47 – 3441-6131

ORTHO BITE

Test	Specification	Results
Sensitivity to environment lighting – ISO 4049	According to the ISO 4049 standard, acceptance is related to the physical homogeneity of the sample, so the material was compared after the test to the same material pressed between coverslips, but without exposure to ambient light. Thus, there is no difference between the samples.	All results are within the range specified by ISO 4049.
Depth of Cure - ISO 4049	According to ISO 4049, the specification for this material is that its curing depth is: > 1.0 mm for opaque materials and > 1.5 mm for non-opaque materials.	All results are greater than the specified threshold, therefore the material is considered to be in conformity.
Flexural strength	According to the EN ISO 4049 standard the specification for flexural strength is ≥50MPa.	All results are greater than the specified threshold, therefore the material is considered to be in conformity.
Water sorption and solubility.	Sorption: Maximum of 40 µg/mm³. Solubility: maximum of 7.5 µg/mm³.	The results demonstrate that the product complies the specification in the EN ISO 4049 Standard.
Accelerated Stability Studies	Study created to accelerate the possible chemical degradation and/or physical changes of the product in forced conditions of storage.	Considering the results observed at the end of the 227 days test period, the shelf-life of 3 years in the storage condition of 27°C for the product can be confirmed.
Evaluation Report of Long-Term Stability (Shelf)	Study designed to verify the physical and chemical characteristics of the product during the expected shelf life. The results are used to confirm the expiration date and storage conditions.	Considering the results observed at the end of the 36 months of the long-term test (shelf), the shelf life of 3 years in the storage condition of 30°C for the product can be confirmed.
Transport evaluation report	We performed a testing according to ASTM D4169	The testing results were successful and we had only aesthetic damages considered irrelevant. However, initially the test report advised that the packages did not meet the minimum criteria for compression testing. Therefore, a new testing was performed aiming to re-evaluate the paperboard compression resistance. DENTSCARE modified the paperboard specs and submitted to CETEA to repeat the assessment. According to TEST REPORT CETEA RE 07.217/17, all evaluated samples met the compression criteria required by ASTM D4169 standard.
Shear Bond Strength – ISO 29022	According to ISO 29022 standard, the test verifies the adhesive bond strength between direct dental restorative materials and tooth structure. The results are used to confirm the adhesion of the product to the teeth surface.	Orthocem: 14.70 MPa Ortho Bite: 14.76 MPa Transbond XT: 15.44 MPa

Conclusion: Based on the performance test applied to these Orthocem and Ortho Bite and the predicate comparison, we conclude that the subject devices are substantial equivalent with the predicate.