August 14, 2020

American Orthodontics
% Rafael Aguila
Responsible Third-Party Official
Accelerated Device Approval Services, LLC
6800 S.W. 40th Street, Ste. 403
Ludlum, Florida 33155

Re: K202276
Trade/Device Name: BracePaste Band and Build LC
Regulation Number: 21 CFR 872.3750
Regulation Name: Bracket adhesive resin and tooth conditioner
Regulatory Class: Class II
Product Code: DYH
Dated: August 10, 2020
Received: August 11, 2020

Dear Rafael Aguila:

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)*
K202276

Device Name
BracePaste™ Band and Build LC

Indications for Use *(Describe)*
A light cure orthodontic band cement intended to bond orthodontic bands 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.

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

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K202276

510(k) Summary

21CFR807.92

Preparation Date: May 19, 2020

Company Information:

American Orthodontics
3524 Washington Avenue
Sheboygan, WI 53081
Phone: 920-457-5051
Fax: 920-457-5773

Submitter Information:

Andre Leak / Regulatory Affairs Coordinator

Device Information:

Trade Name: BracePaste™ Band and Build LC
Common Name: Orthodontic Band Cement
Classification Name: Adhesive, Bracket And Tooth Conditioner, Resin
510(k) Number: unknown
Product Code: DYH
Regulation Number (21CFR): 872.3750

Predicate Device Information:

Product/Trade Name: Light-cured orthodontic band cement (Band Secure)
Classification Name: Adhesive, Bracket And Tooth Conditioner, Resin
510(k) Number: K001446
Product Code: DYH
Regulation Number (21CFR): 872.3750

Description of the Device:

American Orthodontics' BracePaste Band and Build LC is a light-cure band cement that is intended to bond orthodontic bands to teeth.

When an orthodontic band is required for orthodontic treatment, band cement is applied to the inside of the orthodontic band and then the band is seated onto the tooth. Once the band is seated properly, excess adhesive is cleaned up from the proximity of the band and tooth and the adhesive is cured via curing light. The polymerization of the adhesive forms a bond between the orthodontic band and / or the tooth enamel. Upon completion of orthodontic treatment, the orthodontic band is removed and any adhesive remaining on tooth enamel is cleaned up and removed from the tooth.

Indications for Use:

A light cure orthodontic band cement intended to bond orthodontic bands to teeth.

Substantial Equivalence Discussion:

BracePaste Band and Build LC has the following similarities to the legally marketed predicate Light-Cured Orthodontic Band Cement (K001446):

- Same intended use, and

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- Same technological characteristics through delivery system, chemical characteristics, curing method, consistency, and incorporation of similar materials.

The table below outlines the comparison of the predicate device (Light-Cured Orthodontic Band Cement), and American Orthodontics' device (BracePaste Band and Build LC) to show substantial Equivalence.

	Device Name / Manufacturer	
Element	**Device: Light-Cured Orthodontic Band Cement Manufacturer: Scientific Pharmaceuticals, Inc.**	**Device: BracePaste Band and Build LC Manufacturer: American Orthodontics**
510(k) Number	K001446	unknown
Classification Code/ Regulation Number	DYH 872.3750	DYH 872.3750
Intended Use	Light-cure orthodontic band cement is intended for use in cementation of orthodontic bands on teeth requiring application of forces exceeding the capacity of bonded brackets.	A light cure orthodontic band cement intended to bond orthodontic bands to teeth.
Delivery System	Clinician applies a manual load to the plunger to dispense adhesive from the tip of the syringe or the carpule.	Clinician applies a manual load to the plunger to dispense adhesive from the tip of the syringe or the carpule.
Cement Type	Resin-Based	Resin-Based
Physical Form	Paste	Paste
Curing Method	Light Activated	Light Activated

Performance Testing:

Clinical Performance Testing

No clinical performance testing has been conducted.

Non-Clinical Performance Testing

The following non-clinical performance tests were conducted:

1. Shear Bond Strength Test (ISO 29022:2013) – predicate device
2. Accelerated Aging Stability Test
3. Interaction with Accessories

The combination of in-house testing and side-by-side comparison performed by the original manufacturer has demonstrated the efficacy or suitability to the intended purpose of the BracePaste Band and Build LC.

Conclusion:

The combination of in-house testing and side-by-side comparison performed by the original manufacturer has demonstrated the efficacy and suitability to the intended purpose of the BracePaste Band and Build LC orthodontic band adhesive. Results of bench testing indicate that BracePaste Band and Build LC performs as well as the predicate Light-Cured Orthodontic Band Cement.
Both devices have the same intended use – to bond orthodontic bands to teeth.
Any slight differences do not affect the original function or intended purpose of the device.

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Information contained in this 510(k) does not raise new questions or safety and effectiveness and, demonstrates BracePaste Band and Build LC is at least as safe and effective as the predicate.