DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Lang Dental Manufacturing Co., Inc.
Dave Lang
President
175 Messner Drive Po Box 969
Wheeling, Illinois 60090

May 31, 2017

Re: K163482
Trade/Device Name: Orthodontic Acrylic 2
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: February 27, 2017
Received: March 3, 2017

Dear Dave Lang:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mary S. Runner -S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Orthodontic Acrylic 2

Indications for Use *(Describe)*
Orthodontic Acrylic 2 is intended for the fabrication of methacrylate-based orthodontic appliances (such as retainers, bite guards, and bite plates, etc.)

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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510(k) SUMMARY

Applicant: Lang Dental Manufacturing Company Incorporated
175 Messner Drive
P. O. Box 969
Wheeling, Illinois 60090-0969

Contact Person: David Lang
Tel: 847-215-6622
Fax: 847-215-6678

Date Prepared: 30 May, 2017

Trade Name: Orthodontic Acrylic 2
Common Name: Fast Curing Orthodontic Acrylic Resin Powder and Liquid

Product Code: EBI
Classification/Name: Denture relining, repairing, or rebasing resin
Class II per CFR 872.3760

Predicate Devices:

Orthodontic Acrylic 2 is substantially equivalent to the following Lang Dental Manufacturing Company Incorporated's:

Orthodontic Acrylic, K141439

Indications for Use:

Orthodontic Acrylic 2 is intended for the fabrication of methacrylate-based orthodontic appliances (such as retainers, bite guards, and bite plates, etc.).

Description of Applicant Device:

Orthodontic Acrylic 2 is a fast curing self-cure 2 part system. The system consists of a powder and a liquid. The combination of the powder and liquid is converted into a hard methacrylate finished product.

Technological Characteristics:

Orthodontic Acrylic 2 is based upon industry standard chemistry. The Orthodontic Acrylic 2 Liquid contains Quaternary Ammonium Methacryloxy Silicate (QAMS). Since QAMS is co-polymerizable, the antibacterial/antifungal properties are independent of loss of surface layer since it is incorporated throughout the entire polymer network. In-vitro testing of Orthodontic Acrylic 2 shows that QAMS inhibits adhesion of Candida albicans and reduces Streptococcus mutans and Actinomyces naselunii for at least 3 months.

Orthodontic Acrylic 2 containing QAMS has been shown in a limited clinical study involving 32 patients to reduce biofilm formation on the surface of the appliance, as compared to Orthodontic Acrylic that does not contain QAMS. In addition, in-vitro studies conducted after three months showed a substantial reduction in S. mutans, A. naeslundii and C. albicans biofilm formation on the device. QAMS in Orthodontic Acrylic 2 aids in keeping the oral appliance clean and is not a substitute for regular cleaning of the appliance by the patient. A reduction in biofilm on the surface of appliance has not been shown to have enhanced clinical outcomes.

The indications for use of Orthodontic Acrylic 2 are the same as those for Orthodontic Acrylic and are summarized in the table below:

Orthodontic Acrylic	**Orthodontic Acrylic 2**
Orthodontic Acrylic is intended for the fabrication of methacrylate-based orthodontic appliances (such as retainers, bite guards, and bite plates, etc.).	Orthodontic Acrylic 2 is intended for the fabrication of methacrylate-based orthodontic appliances (such as retainers, bite guards and bite plates, etc.).

Comparison of the chemical composition of Orthodontic Acrylic 2 to the predicate is provided in the following table:

Chemical Composition	**Orthodontic Acrylic**	**Orthodontic Acrylic 2**
Formulation	Methacrylate liquid	Methacrylate liquid
Formulation	Powder	Powder
Presentation	2-part system	2-part system
Polymerization	Self-Cured	Self-Cured
Additional Feature	Anti-bacterial/ Anti-Fungal Agent	Anti-bacterial/ Anti Fungal Agent

Performance Date:

The following physical/mechanical properties of Orthodontic Acrylic 2 were tested:

Physical / Mechanical Property	**Orthodontic Acrylic 2**
Flexural Strength (ISO 20795-2:2010)	Orthodontic Acrylic 2 meets the requirements of ISO 20795-2:2010 for flexural strength
Flexural Modulus (ISO 20795-2:2010)	Orthodontic Acrylic 2 meets the requirements of ISO 20795-2:2010 for flexural modulus
Fracture Toughness (ISO 20795-2:2010)	Orthodontic Acrylic 2 meets the requirements of ISO 20795-2:2010 for fracture toughness
Water sorption (ISO 20795-2:2010)	Orthodontic Acrylic 2 meets the requirements of ISO 20795-2:2010 for water sorption.
Water Solubility (ISO 20795-2:2010)	Orthodontic Acrylic 2 meets the requirements of ISO 20795-2:2010 for water solubility.

Physical / Mechanical Property	Orthodontic Acrylic 2
Anti-Bacterial Testing (in vitro)	Orthodontic Acrylic 2 is equivalent to the predicate against S. mutans and A. naeslundii.
Anti-fungal testing (in vitro)	Orthodontic Acrylic 2 is equivalent to the predicate against C. albicans.

Biocompatibility:

An evaluation of biocompatibility was conducted using ISO 10993-1:2009 to determine the biological testing requirements for Orthodontic Acrylic 2.

Orthodontic Acrylic 2 was tested for Guinea Pig Maximization Sensitization Testing and Oral Mucosal Irritation (ISO 10992-10) and cytotoxicity (ISO 10993-5); Orthodontic Acrylic 2 met the requirements for these tests.

Conclusion:

Side by side comparisons demonstrate that the applicant device is substantially equivalent in safety and effectiveness to the predicate device.