510 (k) SUMMARY

Applicant: Lang Dental Manufacturing Company Incorporated
175 Messner Drive
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Wheeling, Illinois 60090-0969

Contact Person: David Lang
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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 Candidaalbicans 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.

From: **Adjodha, Michael E** <Michael.Adjodha@fda.hhs.gov>
Date: Tue, May 30, 2017 at 7:51 AM
Subject: RE: Request for K163482, Orthodontic Acrylic 2

Good morning all,
I hope you all had a nice holiday weekend. I would like to follow up on the request for the following:

1.) A revised 510(k) Summary -- Under the **technological characteristics** section, second paragraph, the text should read as follows:

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.*

2.) A statement (from the official contact) that the labeling (including the instructions for use) will contain the text highlighted above prior to marking the device.

I would appreciate if you could send this at your earliest convenience. The submission is currently on day 88 of 90. If there are any questions or concerns please contact me at 301-796-6276.

Thank you,
Michael

Michael E. Adjodha, MChE
Chemical Engineer
ODE/DAGRID/DEDB
WO66-G308
Center for Devices and Radiological Health
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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

June 02, 2016

KIMMERLING HOLDINGS GROUP C/O REGISTRAR CORP.
144 RESEARCH DRIVE
HAMPTON, VA 23666
UNITED STATES

Dear Sir / Madam

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) acknowledges receipt of your submission. this submission has been assigned the following unique document control number. Failure to reference this assigned number in future correspondence may result in processing delays.

Master Access File Number: MAF2174/A007
Device: K18 QAMS
Received: 06/02/2016

You may ammend this master access file (MAF) to include additional information at any time. All amendments shall be sumitted in duplicate, identified with the above MAF number, and addressed to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Information in your MAF may be incorporated by your client in their premarket approval applications (PMAs), investigational device exemptions (IDEs), premarket notification submissions (510(k)s), reclassification petitions, color additive petitions, or other submission types to FDA.

Only you can authorize reference to your MAF. In order to prevent your client's submission from being found deficient for lack of an authorization letter to reference your MAF and to expedite processing, please provide a signed authorization letter directly to your client with the instruction that the original of your letter be included in the original copy of the client's submission along with a copy in each additional copy. Under this approach, your MAF need not be amended to include the letter of authorization.

If you have any questions concerning this letter, please contact Ms. Wanda Sawyer-Major at (301) 796-6568 or by email at wanda.sawyer-major@fda.hhs.gov

Sincerely yours,

Joshua Nipper, M.E.
Acting Director
Premarket Approval Application Program
Office of Device Evaluation
Center for Devices and Radiological Health