October 4, 2019

Tokuyama Dental Corporation
% Keith Barritt
Principal
Fish & Richardson P.C.
1001 Maine Ave., SW, Suite 1000
Washington, District of Columbia 20024

Re: K190940
Trade/Device Name: Tokuyama Rebase III
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: September 5, 2019
Received: September 6, 2019

Dear Keith Barritt:

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 Nandkumar, Ph.D.
Acting 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)*
K190940

Device Name

TOKUYAMA REBASE III

Indications for Use *(Describe)*

The TOKUYAMA REBASE III device is for relining dentures and extension of denture borders.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
Tokuyama Dental Corporation
TOKUYAMA REBASE III
Denture relining, repairing, and rebasing resin

Submitter

(i) 510(k) Submitter

Tokuyama Dental Corporation
38-9 Taitou 1-chome, Taitou-ku
Tokyo 110-0016
Japan
Phone: 011-81-3-3835-2261

(ii) 510(k) Submitter Contact

Keith A. Barritt
Fish & Richardson P.C.
1000 Maine Ave., S.W, Suite 1000
Washington, DC 20024
Phone: (202) 783-5070
Facsimile: (202) 783-2331
Email: barritt@fr.com

(iii) Preparation Date

September 5, 2019

Device

Trade or Proprietary Name:	TOKUYAMA REBASE III
Common Name:	denture relining, repairing, or rebasing resin
Classification Name:	resin, denture, relining, repairing, rebasing
Product Code:	EBI, 21 CFR 872.3760
Class:	2

Predicate Device

Primary Predicate: GC America, Inc.'s GC RELINE (K#982695).

Reference Devices for purposes of establishing biocompatibility (i.e. all ingredients of the TOKUYAMA REBASE III are already cleared for marketing in similar Tokuyama devices): TOKUSO REBASE (K#896981), TOKUYAMA REBASE II (K#022641), TOKUYAMA CURECGRACE (K#170549), and PALFIQUE ESTELITE PASTE (K#980051).

Device Description

The TOKUYAMA REBASE III device is an acrylic resin used for chairside hard denture linings and extension of denture borders. The powder contains poly(ethyl methacrylate) and benzoyl peroxide. The liquid contains methacrylate monomer. The REBASE adhesive contains ethyl acetate, acetone and methacrylate polymer. The REBASE adhesive is used solely for bonding to acrylic surfaces, and cannot be used to bond nylon, metal, and silicone surfaces, etc.

The device is composed of both a powder and liquid that is cured by chemical polymerization. The powder is packaged in a plastic bottle, and the liquid is packaged in a glass bottle. A group of polymerization agents of the device is contained in the powder and liquid separately to avoid the reaction during storage, and the polymerization reaction starts by mixing the powder and liquid. The device is cured by polymerization of methacrylic monomers contained in the liquid.

The TOKUYAMA REBASE III kit contains powder, liquid, REBASE adhesive, TOKUSO RESIN HARDENER II, and other accessories, namely, a measuring cup, dropper, rubber cup, spatula, drip nozzle, drip cup, brush, and spoon.

The TOKUYAMA REBASE III device, like the primary predicate K#982695, is regulated under FDA product code EBI, 21 CFR 872.3760.

The device does not come sterile and is not intended to be sterilized prior to use.

The powder comes in "fast" and "normal" depending on the desired setting time, and in three shades designated as Light Pink, Pink, and Live Pink.

Indications for Use

The TOKUYAMA REBASE III device is for relining dentures and extension of denture borders

Comparison of Technological Characteristics

The TOKUYAMA REBASE III device has the same basic technological characteristics in terms of design, material, and chemical composition as the predicate device identified above. The TOKUYAMA REBASE III device does not have its own energy source.

For purposes of performance characteristics for obtaining FDA marketing authorization, the TOKUYAMA REBASE III is substantially equivalent to GC America Inc.'s GC RELINE (K#982695), as shown below:

	Subject device	Primary predicate	Difference
Device name	TOKUYAMA REBASE III	GC RELINE	-
Manufacturer	Tokuyama Dental	GC America Inc.	-
510(k) No.	(Pending)	K982695 (Bonding agent is separately authorized under K963144)	-
Classification name	Resin, Denture, Relining, Repairing, Rebasing	Resin, Denture, Relining, Repairing, Rebasing	-
Product Code	EBI	EBI	
Device Class	2	2	
Indications for Use	Relining dentures and extension of denture borders	GC Reline is an acrylic resin for direct denture linings and extension of denture borders [2)]	Similar The Indications for Use of the subject device are within those of the predicate device.
Component	Powder, Liquid, and Adhesive	Powder, Liquid, and Bonding agent	Similar It only differs in expression of adhesive, there are no differences in components.
Principle of operation	Acrylic resin that is cured by chemical polymerization reaction starting with mixing powder and liquid component (Self – curing acrylic resin).	Acrylic resin that is cured by chemical polymerization reaction starting with mixing powder and liquid component (Self – curing acrylic resin).	Identical
Sterilization	Not provided sterile and not intended to be sterilized	Not provided sterile and not intended to be sterilized	Identical

Material	Powder	- Poly(ethyl methacrylate) - Benzoyl peroxide	- Poly(ethyl methacrylate) - Benzoyl peroxide	Identical
	Liquid	- Methacrylate monomer	- Benzyl methacrylate - Dimethacrylate - 1,6-hexanediyl bismethacrylate - Catalyst - UV-light absorber	Similar The subject device consists mainly of methacrylates as with the predicate device. Since all of the ingredients to be used in the subject device have already been used in such existing devices, the safety of subject device is assured.
	Adhesive	REBASE Adhesive - Ethyl acetate - Acetone - Mthacrylate polymer	Bonding agent - Methyl methacrylate (MMA) - Acetone - 2-Hydroxyethyl methacrylate (HEMA)	Similar The subject device contains organic solvents as a part of its ingredients as with the predicate device. Since all of the ingredients to be used in the subject device have already been used in such existing devices, the safety of subject device is assured.

Shelf Life Testing

Shelf life test data of TOKUYAMA REBASE III based on ISO 20795-1 are not available. However, Tokuyama conducted real-time shelf-life testing to establish a shelf life of three years at a temperature between 0-25°C (32-77F°) based on JIS T 6521, and no deterioration is expected in real time shelf life data based on the ISO standard. In particular, since deterioration of curability is easily observed as deterioration of surface hardness, water absorption, and water solubility, it is expected that there will be no deterioration in flexural properties, which is one of the indicators of curability.

Material And Chemical Composition

For purposes of performance, as noted above the primary predicate is GC America, Inc.'s GC RELINE (K#982695).

For purposes of material and chemical composition, the TOKUYAMA REBASE III device has the same basic characteristics as Tokuyama's own TOKUSO REBASE (K#896981), TOKUYAMA REBASE II (K#022641), TOKUYAMA CURECGRACE (K#170549), and PALFIQUE ESTELITE PASTE (K#980051). Thus, no further biocompatibility testing was conducted on the device.

Tokuyama examined the biocompatibility of TOKUYAMA REBASE III according to ISO 10993-1: 2009 and the FDA's related guidance "Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process." As a result of comparing of each ingredient and its purpose of use, operating principle, manufacturing process, nature of body contact, contact duration, and other factors with existing devices, it was concluded that TOKUYAMA REBASE III has no new biocompatibility risk and required no further biocompatibility tests.

Performance Data Summary

Tokuyama examined the performance based on ISO 20795-1: 2013, including testing of the cured material for surface characteristics, polishability, shape capability, color stability, translucency, porosity, water sorption, and water solubility, and TOKUYAMA REBASE III conforms to the standard for each characteristic, as does the primary predicate GC America, Inc.'s GC RELINE (K#982695).

"Residual methyl methacrylate monomer" was not applicable as the material does not contain methyl methacrylate monomer. "Colour match" test could not be conducted because the material has no shade guide. "Bonding to artificial teeth" data were not available, but the need for the test was low as relining material

tends to be applied to the mucosal surface of the denture base in a thin layer, and not applied to the occlusal surface, so it does not contact with artificial teeth. Because the TOKUYAMA REBASE III device is not impact resistant, related tests were not conducted.

Additional non-clinical testing of the physical properties of the TOKUYAMA REBASE III device was conducted in accordance with JIS T 6521:2005 "Denture Base Hard Relining Materials," including testing of the cured material for consistency, peak temperature, porosity and defects, surface gloss, water sorption, water solubility, and hardness, and TOKUYAMA REBASE III conforms to the standard for each characteristic, as does the primary predicate GC America, Inc.'s GC RELINE (K#982695).

There were no clinical tests performed for the TOKLUYAMA REBASE III device.

Conclusion

Based on the non-clinical testing conducted of the physical properties of the TOKUYAMA REBASE III device in comparison to the predicate device identified above, and on the biocompatibility of FDA-authorized devices for the same use with the same ingredients, it is concluded that the TOKUYAMA REBASE III device is substantially equivalent to the predicate device.