DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Tokuyama Dental Corporation
c/o Mr. Keith Barritt
Fish & Richardson
1425 K Street, N.W.
Suite 1100
Washington, DC 20005

July 5, 2017

Re: K170549
Trade/Device Name: TOKUYAMA CUREGRACE
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI and EBG
Dated: May 30, 2017
Received: May 31, 2017

Dear Mr. 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. 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" (21CFR 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 -A

Lori A. Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Change Control Table, Change History

Change Control Table

Version	Document Author	Document Approver	Date Approved
1.00	Name, Title, Office	Name, Title, Office	MM/DD/YYYY

Complete Change Control Table (all versions) retained in SWIFT Docs.

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
TOKUYAMA CUREGRACE

Indications for Use *(Describe)*

The TOKUYAMA CUREGRACE device is an acrylic resin used in a variety of dental applications such as:

- Temporary inlay, crowns and bridges
- Repair of broken or cracked dentures
- Denture border extension
- Replacement of lost denture teeth
- Adjustment of the occlusal height of resin 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.

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 CUREGRACE
Self-curing acrylic dental resin

The following information is provided pursuant to 21 CFR 807.92.

807.92(a)(1): Submitter's Name/Address, Contact, and Preparation Date

(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.
1425 K Street, N.W., Suite 1100
Washington, DC 20005
Phone: (202) 783-5070
Facsimile: (202) 783-2331
Email: barritt@fr.com

(iii) Preparation Date

February 14, 2017

807.92(a)(2): Name of Device

Trade or Proprietary Name:	TOKUYAMA CUREGRACE
Common Name:	denture relining, repairing, or rebasing resin and temporary crown and bridge resin
Classification Name:	resin, denture, relining, repairing, rebasing crown and bridge, temporary, resin
Product Code:	EBI, 21 CFR 872.3760 EBG, 21 CFR 872.3770

807.92(a)(3): Predicate Devices

The TOKUYAMA CUREGRACE acrylic dental resin is substantially equivalent for purposes of FDA medical device regulations to the primary predicate, the GC UNIFAST TRAD (K#984365), The devices share the same intended use and there are no new questions of safety or effectiveness. The GC America UNIFAST III device is also very similar and shares some particular Indications with the TOKUYAMA CUREGRACE device, as shown below:

Device name	TOKUYAMA CUREGRACE	Primary predicate device GC UNIFAST TRAD	Reference device UNIFAST III
Manufacturer	Tokuyama Dental Corporation	GC America Inc.	GC America Inc.
510(K) number	(Pending)	K984365	K073106
Device classification name	- Resin, denture, relining, repairing, rebasing - Crown and bridge, temporary, resin	- Resin, denture, relining, repairing, rebasing - Crown and bridge, temporary, resin	- Resin, denture, relining, repairing, rebasing - Crown and bridge, temporary, resin
Product code	EBI, EBG	EBI, EBG	EBI, EBG
Indications for use	Acrylic resin used in a variety of dental applications, such as - Temporary inlay, crowns and bridges - Repair of broken or cracked dentures - Denture border extension - Replacement of lost denture teeth - Adjustment of the occlusal height of resin teeth	Acrylic resin used in a variety of dental applications such as repair of full or partial acrylic dentures. Construction of temporary crowns. Impression trays for individual teeth. Check bit registration. Construction and repair of orthodontic plates and splints.	Self-curing acrylic resin used for a variety of dental application, including construction of temporary inlays, crowns and bridges and repair of fractured dentures in either pressure or paint on techniques.
Components	Powder and liquid	Powder and liquid	Powder and liquid
Principle of operation	Acrylic resin that is cured by chemical polymerization reaction starting with mixing the powder and liquid component. (Self-curing acrylic resin)	Acrylic resin that is cured by chemical polymerization reaction starting with mixing the powder and liquid component. (Self-curing acrylic resin)	Acrylic resin that is cured by chemical polymerization reaction starting with mixing the powder and liquid component. (Self-curing acrylic resin)

807.92(a)(4): Device Description

The TOKUYAMA CUREGRACE device is a self-curing acrylic dental resin used for denture relining, repairing, or rebasing and for temporary crowns and bridges. 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.

The powder comes in four shades designated as A2, A3, Pink, and Live Pink.

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

The TOKUYAMA CUREGRACE device comes with a measuring cup for measuring the powder component and a dropper for dispensing the liquid component. The measuring cup is made from standard polypropylene, and the material has been used for the measuring cup of Tokuyama's own "Tokuyama Rebase II" device (K#022641). The dropper is made from standard polyethylene or ethylene-vinylacetate copolymer. The polyethylene has been used for the dropper of the "Tokuyama Rebase II" device and the ethylene-vinylacetate copolymer has been used for the dropper of Tokuyama's own "Tokuso Curefast" device authorized in Japan since 1998.

807.92(a)(5): Intended Use

The TOKUYAMA CUREGRACE device is an acrylic resin used in a variety of dental applications such as:

- Temporary inlay, crowns and bridges
- Repair of broken or cracked dentures
- Denture border extension
- Replacement of lost denture teeth
- Adjustment of the occlusal height of resin teeth

807.92(a)(6): Technological Characteristics

The TOKUYAMA CUREGRACE uses mostly the same materials as have been cleared by the FDA for similar uses. For the new ingredients, Tokuyama has conducted robust biocompatibility testing.

The design of the device is similar to the predicate device as demonstrated above.

807.92(b)(1): Non-clinical Testing

The TOKUYAMA CUREGRACE device was tested for conformance and/or developed in accordance with the following FDA-recognized standards:

ISO 10993-1:2009 Biological evaluation of medical devices

ISO 7405: 2008 Dentistry – Evaluation of biocompatibility of medical devices

ISO 10477:2004 Dentistry – Polymer-based crown and bridge materials

ISO 14971 Second Edition 2007-03-01 Medical Devices – Application of Risk Management to Medical Devices

In addition, the device has been evaluated pursuant to the following non-FDA recognized standard:

> ISO 20795-1:2013 Dentistry – Base polymers – Part 1: Denture base polymers

807.92(b)(2): Clinical Testing

There were no clinical tests performed for the TOKUYAMA CURECRACE device.

807.92(b)(3): Conclusions from Testing

Based on the comparison of the TOKUYAMA CUREGRACE device to the primary predicates identified above and based on the non-clinical testing described above, it is concluded that the TOKUYAMA CUREGRACE device is substantially equivalent to the primary predicate device.