DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

March 3, 2016

GC America, Inc.
Mr. Mark Heiss
Director, Regulatory & Academic Affairs
3737 W. 127th St.
Alsip, Illinois 60803

Re: K153253
Trade/Device Name: GC Reline II
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: February 1, 2016
Received: February 3, 2016

Dear Mr. Heiss:

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 yours,

for Erin I. Keith, M.S.
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)*
K153253

Device Name

GC Reline II

Indications for Use *(Describe)*

GC RELINE II is a resilient material for making soft relining of dentures.

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.

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K153253

510(k) Summary

Date Prepared: February 29, 2016

1. Submitter Information:

GC AMERICA INC.
3737 W. 127th Street
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Contact Person: Mark Heiss, D.D.S.
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2. Device Name:

Proprietary Name: GC RELINE II
Classification Name: Denture relining, repairing or rebasing resin
CFR Regulation: 21CFR 872.3760
Device Classification: Class II
Product Code: EBI

3. Predicate Device:

Company	Device	510(k)	Date Cleared
GC America, Inc.	GC Reline Soft/Extra Soft	K990376	March 5, 1999

4. Description of Device:

GC RELINE II is a VPS silicone for relining of dentures. The components consist of the base silicone paste and the catalyst silicone paste that are extruded from a cartridge and are automixed with a mixing tip. GC Reline II is available in the following viscosities: Soft, Extra Soft, and Extra Extra Soft.

The cartridge is made of high density polyethylene and the cap is made of polypropylene. The mixing tip is made of polypropylene.

GC Reline Primer for Resin is a resin adhesive that is packaged in a glass bottle.

GC Reline Modifier is available in Liquid A and Liquid B and is similar to the Base and Catalyst of the subject device. Liquid A and Liquid B are dispensed in equal amounts onto the mixing pad and mixed together. It is used to modify (activate) the existing reline surface to accept additional Reline II material.

5. Indications for Use:

GC RELINE II is a resilient material for making soft relining of dentures.

6. Technological characteristics:

The components of GC RELINE II and the predicate device are similar. The subject device GC Reline II contains a new ingredient, Polydimethylsiloxane, which is used in each of the three viscosities. Bench testing demonstrates that the addition of the new ingredient does not impact technological characteristics when compared to the predicate K990376. The curing mechanism of the applicant and predicate devices is by polymerization of uncured vinyl polysiloxane. This reaction is caused by chemical polymerization initiator systems. Bench top testing indicates that even with different formula, applicant device and predicate devices, meet specifications listed in ISO 10139-2.

Therefore, the applicant and predicate device are substantially equivalent. There are no statistically significant differences between GC RELINE II and GC RELINE when comparing performance data.

	Applicant device	Primary Predicate
Product category	CHAIRSIDE VINYL POLYSILOXANE RESILIENT DENTURE LINER	CHAIRSIDE VINYL POLYSILOXANE RESILIENT DENTURE LINER
Trade name	GC RELINE II	GC RELINE (Soft/ Extra Soft)
510(k) Number	K153253	K990736
Indications for Use	GC RELINE II is a resilient material for making soft relining of dentures.	GC RELINE Soft *I* Extra Soft is a resilient material for making soft relining of dentures.
Device Description	GC RELINE II is a VPS silicone for relining of dentures. The device consists of the base paste and the catalyst paste Including VPS. The material sets by mixing the catalyst paste with the base paste.	GC RELINE is a VPS silicone for relining of dentures. The device consists of the base paste and the catalyst paste Including VPS. The material sets by mixing the catalyst paste with the base paste.
Device Components	Base: Silicon dioxide Vinyldimethylpolysiloxane Methylhydrogen dimethylpolysiloxane Polydimethylsiloxane* Colorant Catalyst: Silicon dioxide Vinyldimethylpolysiloxane Polydimethylsiloxane* Platinum Catalyst	Base: Silicon dioxide Vinyldimethylpolysiloxane Methylhydrogen dimethylpolysiloxane Methylphenylpolysiloxane Colorant Catalyst: Silicon dioxide Vinyldimethylpolysiloxane Platinum Catalyst
Similar Physical Properties (tested in accordance with ISO 10139-2)	Shore A hardness, 24h Shore A hardness, 28d Bond strength (MPa) Sorption($\mu g/mm^3$) Solubility ($\mu g/mm^3$)	Shore A hardness, 24h Shore A hardness, 28d Bond strength (MPa) Sorption($\mu g/mm^3$) Solubility ($\mu g/mm^3$)
Composition of Materials	Cartridge – high density polyethylene Cap – polypropylene Mixing tip - polypropylene. GC Reline II Primer for Resin- 8g glass bottle. GC Reline II Modifier–polypropylene bottle. GC Reline II Remover–high density polyethylene.	Cartridge – high density polyethylene Cap- polypropylene Mixing tip - polypropylene. GC Reline II Primer for Resin – 8 g glass bottle. GC Reline II Modifier- polypropylene bottle.
Standards of Conformity	ISO 10139:2009, Sections 5.1, 5.2, 5.3 IS010993-1:2009, Sections 6.2.2.2, 6.2.2.3, 6.2.2.4 ISO 10993-2:2006 ISO 10993-5:2009 Sections 8.5 ISO 10993-10:2010, Sections 6, 7	Not available
Biocompatibility	10993-5 Cytotoxicity – pass 10993-10 irritation - pass 10993-10 sensitization – pass	Not available

Biocompatibility Testing

Test	Test Standard	Test Results (pass or fail)
Cytotoxicity Test	Under the conditions of ISO 10993-1:2009, Biological evaluation of medical devices, sections 6.2.2.2, 6.2.2.3, 6.2.2.4, the test articles should meet the test requirements	Pass
Cytotoxicity Test In Vitro	Under the conditions of ISO 10993-5:2009, Biological evaluation of medical devices, section 8.5 Determination of cytotoxicity, the test articles should meet the test requirements	Pass
Irritation and Sensitization	Under the conditions of ISO 10993-10:2010, biological evaluation of medical devices, Sections 6, 7, the test articles should meet the test requirements	Pass

7. Nonclinical Testing:

Benchtop testing demonstrates that the subject device GC Reline II, like its predicate device GC Reline Soft/Extra Soft, is in compliance with ISO 10139-2:2009 Dentistry-Soft lining materials for removable dentures-Part 2: Materials for long-term use, and as such, the subject device meets specific requirements for softness, adhesion, water sorption and water solubility as well as for packaging, marking and manufacturer's instructions for soft denture lining materials suitable for long-term use. The subject device GC Reline II was also tested and met the requirement for cytotoxicity, irritation and sensitivity as shown in the biocompatibility table above.

8. Substantial equivalence:

The subject device GC RELINE II and its predicate device GC RELINE (Soft/ Extra Soft) share the same function and intended use. The curing mechanism of the new and predicate device is equivalent. Bench testing demonstrates that the addition of a new ingredient in the subject device does not impact technological characteristics when compared to the predicate K990376.

The subject device and predicate devices encompass the same range of physical dimensions, including hardness, bond strength, sorption, solubility, and also share equivalent biocompatibility. Both the subject and predicate devices are provided nonsterile and have a shelf life of 2 years. Any differences in the technological characteristics do not raise new questions.

GC AMERICA INC. has demonstrated that, for the purposes of FDA's regulation of medical devices, the subject device GC Reline II is substantially equivalent to the predicate device in intended use, material composition, fundamental scientific technology, principals of operation, and basic design.