GC America Inc.
Mark Heiss, DDS
Director, Regulatory Affairs
3737 W. 127th Street
Alsip, Illinois 60803

July 12, 2018

Re: K181011
Trade/Device Name: AIM2
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: ELW
Dated: May 17, 2018
Received: May 21, 2018

Dear Mark 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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

For 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

Section 4 – Indications for Use Statement

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)*

K181011

Device Name

AIM 2

Indications for Use *(Describe)*

AIM2 is a silicone impression material for taking oral impressions.

Type of Use *(Select one or both, as applicable)*

[X] 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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Date Prepared: April 16, 2018

1. Submitter Information:

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2. Device Name:

Proprietary Name: AIM2
Classification Name: Material, Impression
CFR Regulation: 21CFR 872.3660
Device Classification: Class II
Product Code: ELW

3. Predicate Devices:

Company	Device	510(k) No.	Date Cleared
GC America Inc.	EXAFLEX/EXAMIX Impression Material	K955932	March 11,1996

4. Description of Device:

AIM2 is a VPS silicone impression material. 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. AIM2 is available in one viscosity.

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

5. Indications for Use:

AIM2 is a silicone impression material for taking oral impression.

6. Performance Bench Tests

It is confirmed that the device conforms to the required specifications according to ISO 4823 and is suitable for its intended use.

11. Packaging

a) AIM2, 2-Pk; contains two cartridges and 6 mixing tips
b) Mixing Tip II: L

7. Shelf Life Evaluation and Storage Conditions:

- Shelf Life 2 years
- Recommended for optimal performance, store at room temperature. 15-25°C (59.0 - 77.0°F) (Relative humidity: 50%).

Table 5.1.1 Comparison Table

	Applicant device	Predicate device
Product category	Hydrophilic vinyl polysiloxane impression material	Hydrophilic vinyl polysiloxane impression material
Trade name	AIM2	EXAMIX
Manufacturer	GC Corporation	GC Corporation
Indications for use	AIM2 is a silicone impression material for taking oral impression.	EXAMIX is a silicone impression material for taking oral impression.
Product description	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.	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.
Instructions for use	Note: The cartridge and mixing tip provided are compatible with GC Cartridge Dispenser 2. **CARTRIDGE LOADING AND DISPENSING** 1. Lift the release lever of the CARTRIDGE DISPENSER 2. (referred to as the dispenser hereafter) and pull the piston plunger all the way back into the dispenser. Lift the cartridge holder of the dispenser and load the cartridge, ensuring that the V-shaped notch on the flange of the cartridge is facing down. Push the cartridge holder down to hold the cartridge firmly in place. 2. Lift the release lever and push the piston plunger forward until it engages into the cartridge. 3. Remove the cartridge cap by rotating 1/4 turn anti-clockwise. Tilt the cap downward and peel it away from the cartridge. Gently squeeze the dispenser handle to extrude a small amount of material from the two openings at the end of cartridge. Make sure that base and catalyst come out evenly. 4. Align the V-shaped notch on the rim of mixing tip to the V-shaped notch between the cartridge barrels. Push firmly to attach the mixing tip. Then rotate the colored collar of the mixing tip 1/4 turn clockwise to the end of the cartridge. The dispenser is now ready for use. 5. Squeeze the handle several times to extrude the material. After use, do not remove the mixing tip as this will become the storage cap until next use. When replacing the mixing tip, rotate the collar on the mixing tip 1/4 turn anti-clockwise to align the V-shaped notch on the cartridge. Tilt the mixing tip downward and peel it away from the cartridge. 6. Remove and replace the old mixing tip immediately prior to next use. Before attaching a new tip, gently extrude a small amount of material to ensure that base and catalyst are flowing evenly from both openings. If the materials should fail to extrude, remove any hardened materials from the end of the cartridge. 7. To replace the cartridge, lift the release lever and retract the piston plunger fully. Remove the empty cartridge by lifting the cartridge holder and load a new one into the dispenser. **USING THE IMPRESSION MATERIAL** Note: Prior to use, leave the material to stand at room temperature. Cooled or refrigerated material may delay setting.	Note: The cartridge and mixing tip provided are compatible with GC Cartridge Dispenser 2. **CARTRIDGE LOADING AND DISPENSING** 1. Lift the release lever of the CARTRIDGE DISPENSER 2. (referred to as the dispenser hereafter) and pull the piston plunger all the way back into the dispenser. Lift the cartridge holder of the dispenser and load the cartridge, ensuring that the V-shaped notch on the flange of the cartridge is facing down. Push the cartridge holder down to hold the cartridge firmly in place. 2. Lift the release lever and push the piston plunger forward until it engages into the cartridge. 3. Remove the cartridge cap by rotating 1/4 turn anti-clockwise. Tilt the cap downward and peel it away from the cartridge. Gently squeeze the dispenser handle to extrude a small amount of material from the two openings at the end of cartridge. Make sure that base and catalyst come out evenly. 4. Align the V-shaped notch on the rim of mixing tip to the V-shaped notch between the cartridge barrels. Push firmly to attach the mixing tip. Then rotate the colored collar of the mixing tip 1/4 turn clockwise to the end of the cartridge. The dispenser is now ready for use. 5. Squeeze the handle several times to extrude the material. After use, do not remove the mixing tip as this will become the storage cap until next use. When replacing the mixing tip, rotate the collar on the mixing tip 1/4 turn anti-clockwise to align the V-shaped notch on the cartridge. Tilt the mixing tip downward and peel it away from the cartridge. 6. Remove and replace the old mixing tip immediately prior to next use. Before attaching a new tip, gently extrude a small amount of material to ensure that base and catalyst are flowing evenly from both openings. If the materials should fail to extrude, remove any hardened materials from the end of the cartridge. 7. To replace the cartridge, lift the release lever and retract the piston plunger fully. Remove the empty cartridge by lifting the cartridge holder and load a new one into the dispenser. **USING THE IMPRESSION MATERIAL** Note: Prior to use, leave the material to stand at room temperature. Cooled or refrigerated material may delay setting.

	1. Attach an intraoral tip to the mixing tip or load material into a syringe. 2. Inject the mixture onto the prepared teeth. 3. Load the tray with the material. 4. Seat the loaded tray in the mouth within specified working times. 5. Wait for set 3 minutes in the mouth). 6. The obtained impression should be cleaned, then disinfected, utilizing a 2.5% or 3.4% glutaraldehyde, or other appropriate disinfectant, according to the manufacturers label recommendations. 7. Remove the impression and pour a model immediately (if desired). Maximum time for pouring the model is 14 days.	1. Attach an intraoral tip to the mixing tip or load material into a syringe. 2. Inject the mixture onto the prepared teeth. 3. Load the tray with the appropriate material (putty, monophase, heavy body or regular - depending on technique being used). 4. Seat the loaded tray in the mouth within specified working times. 5. Wait for set 4 minutes in the mouth). 6. The obtained impression should be cleaned, then disinfected, utilizing a 2.5% or 3.4% glutaraldehyde, or other appropriate disinfectant, according to the manufacturers label recommendations. 7. Remove the impression and pour a model immediately (if desired). Maximum time for pouring the model is 14 days.
Technological Characteristics	The curing mechanism is described as an addition silicone reaction. It is an addition polymerization between vinyl polysiloxanes and poly-me,-siloxanes hydrogen terminated. A platinum complex is used as a catalyst. A side reaction may occur and release small quantity of hydrogen gas. Therefore, palladium is used as a scavenger. A surfactant is added to allow wettability/hydrophilicity. Setting for AIM2 is 3 minutes in the mouth. Results of benchtop testing indicate the physical properties such as linear dimensional change, elastic recover and strain-in compression met the specification set in ISO 4823. Biological safety test data shows the biocompatibility of the predicate device.	The curing mechanism is described as an addition silicone reaction. It is an addition polymerization between vinyl dimethylpolysiloxane and methylhydrogen dimethylpolysiloxane. A platinum complex is used as a catalyst. A surfactant is added to allow wettability/hydrophilicity. Setting time for Examix is 4 minutes in the mouth. Results of benchtop testing indicate the physical properties such as linear dimensional change, elastic recovery and strain-in compression meet the specification set in ISO 4823. Biological safety test data shows the biocompatibility of the predicate device.

8. Substantial equivalence:

The applicant and predicate device are the same in function and intended use. The curing mechanism of the applicant and predicate device is substantially equivalent in principle. This supports that the compatibility and safety of the applicant device is substantially equivalent to the predicate device.

Although there are slight differences in bench top performance tests, results meet requirements as outlined in ISO 4823:2015.

9. Differences

The following differences are noted: setting time for AIM2 is 3 minutes in the mouth and Examix is 4 minutes in mouth.

10. Conclusion

Based on similarities in intended use, mode of action, chemical composition, and performance testing, AIM2 is substantially equivalent to the selected predicate Examix (K955932).