April 9, 2021

Quest Dental USA Corp.
% Takahiro Haruyama
President
Globizz Corporation
1411 W. 190th Street Suite 200
Gardena, California 90248

Re: K201563
Trade/Device Name: PuRE PMMA Disc
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: Class II
Product Code: EBG
Dated: January 13, 2021
Received: January 13, 2021

Dear Takahiro Haruyama:

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,

Michael E. Adjodha -S

Michael E. Adjodha, M.ChE.
Assistant 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)*

K201563

Device Name
PuRE PMMA Discs

Indications for Use *(Describe)*

Pure PMMA Discs are polymethyl methacrylate blanks used to mill dental long-term temporary crowns and bridges in various CAD/CAM systems until permanent restorations can be delivered. Restorations are designed and manufactured by dental professionals and technicians using open CAD/CAM technology.

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."

5. 510(k) Summary - K201563

5.1. Submitter Information

510(k) Owner/Applicant	Quest Dental USA Corp 17865 Sky Park Circle, Ste. L1 Irvine, CA 92614
Official Correspondent	Takahiro Haruyama Globizz Corporation 1411 W. 190th St., Ste. 200 Gardena, CA 90248 Tel: (310) 538-3860 Email: register@globizz.net
Date Prepared	May 15, 2020

5.2. Device Identification

Trade Name	PuRE PMMA Disc
Common Name	PMMA Disc
Classification Name	Temporary Crown and Bridge Resin
Classification Regulation	872.3770
Review Panel	Dental
Product Code	EBG
Device Class	Class II

5.3. Predicate and Reference Devices

Primary Predicate	510(k) No.: K172281 Device Name: PuRE PMMA Disc Submitter/Applicant: Quest Dental USA Corp.
Reference Devices for Composition and Biocompatibility	510(k) No.: K172281 Device Name: PuRE PMMA Disc Submitter/Applicant: Quest Dental USA Corp.

5.4. Device Description

PuRE PMMA Discs are polymethyl methacrylate blanks used to mill dental long-term temporary crowns and bridges in various CAD/CAM systems until permanent restorations can be delivered. Restorations are designed and manufactured by dental professionals and technicians using open CAD/CAM technology. The discs are provided non-sterile, without any accessories, and are indicated for single use only.

The device is composed of polymethyl methacrylate and pigments. PuRE PMMA discs are available in 23 Monochromatic colors and 20 multilayer colors all with varying thickness (14-40mm):

Table 1: PuRE PMMA Disc Monochromatic colors

Clear						
A0	A1	A2	A3	A3.5	A4	
	B1	B2	B3		B4	
	C1	C2	C3		C4	
		D2	D3		D4	
	BL1	BL2	BL3		BL4	BL5

Table 2: PuRE PMMA Discs MultiLayer shade combinations

MLA1	MLA2	MLA3	MLA3.5	MLA4
MLB1	MLB2	MLB3		MLB4
MLC1	MLC2	MLC3		MLC4
	MLD2	MLD3		MLD4
MLBL1	MLBL2	MLBL3		MLBL4

5.5. Indications for Use Statement

PuRE PMMA Discs are polymethyl methacrylate blanks used to mill dental long-term temporary crowns and bridges in various CAD/CAM systems until permanent restorations can be delivered. Restorations are designed and manufactured by dental professionals and technicians using open CAD/CAM technology.

5.6. Comparison of Device Characteristics

Table 3: Comparison of device characteristics to predicate and reference devices.

	Subject Device	Predicate Device	Comparison
510(k) No.	K201563	K172281	
Applicant	Quest Dental U.S.A. Corp.	Quest Dental USA Corp.	--
Device Name	PuRE PMMA Disc	PuRE PMMA Disc	--
Regulation No.	21 CFR 872.3770	21 CFR 872.3770	Same
Product Code	EBG	EBG	
Indications for use	PuRE PMMA Discs are polymethyl methacrylate blanks used to mill dental long-term temporary crowns and bridges in various CAD/CAM systems until permanent restorations can be delivered. Restorations are designed and manufactured by dental professionals and technicians using open CAD/CAM technology.	PuRE PMMA Discs are polymethyl methacrylate blanks used to mill dental long-term temporary crowns and bridges in various CAD/CAM systems until permanent restorations can be delivered. Restorations are designed and manufactured by dental professionals and technicians using open CAD/CAM technology.	Same.
Technological Characteristics			
How Device is Made	Powder and liquid methacrylate-based resins mixed together, and heat cured	Powder and liquid methacrylate-based resins mixed together, and heat cured	Same.
Composition	PMMA + pigments	PMMA + pigments	Same
Biocompatibility	Biocompatible	Biocompatible	Same.
Physical Properties	Met the acceptance criteria of ISO 10477:2004 and JIS T 6518:2011.	Met the acceptance criteria of ISO 10477:2004 and JIS T 6518:2011.	Same.

5.7. Statement of Substantial Equivalence

The subject device and predicate devices are similar in their intended use, technological characteristics, and composition of construction materials. Standardized performance and biocompatibility assessments, as well as differences between the devices, did not raise any new concerns regarding safety and effectiveness. The conclusions drawn from the non-clinical performance tests demonstrate that the PuRE PMMA Disc is substantially equivalent to the referenced predicate device.