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

October 19, 2017

Re: K172281
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: August 3, 2017
Received: August 4, 2017

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. 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 (DICE) 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 (DICE) 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 -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

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)*

K172281

Device Name
PuRE PMMA Disc

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.

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SECTION 5: 510(k) Summary

K172281

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	July 21, 2017

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

Predicate Device	510(k) No.: K093708 Device Name: TELIO® CAD Submitter/Applicant: Ivoclar Vivadent, Incorporated
Reference Devices for Composition and Biocompatibility	1. 510(k) No.: K151764 Device Name: Yamahachi PMMA Disks Submitter/Applicant: Yamahachi Dental Products USA, Inc. 2. 510(k) No.: K132937 Device Name: Harvest Dental Polymer Blocks (ZCAD) Submitter/Applicant: Harvest Dental Products, LLC 3. 510(k) No.: K973513 Device Name: ESPE Sinfony Opaquer Powder Submitter/Applicant: ESPE GMBH & CO. KG.

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 shades and varying thicknesses (14-30 mm):

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

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 5-A. Comparison of device characteristics to predicate and reference devices.

	Subject Device	Predicate Device	Reference Devices	Comparison
510(k) No.	Not yet assigned	K093708	1. K151764 2. K132937 3. K973513	
Applicant	Quest Dental U.S.A. Corp.	Ivoclar Vivadent	1. Yamahachi Dental Products USA, Inc. 2. Harvest Dental Products, LLC 3. ESPE GMBH & CO. KG.	--
Device Name	PuRE PMMA Disc	TELIO® CAD	1. Yamahachi PMMA Disks 2. Harvest Dental Polymer Blocks (ZCAD) 3. ESPE Sinfony Opaquer Powder	--
Regulation No.	21 CFR 872.3770	21 CFR 872.3770	1. 21 CFR 872.3770 2. 21 CFR 872.3770 3. 21 CFR 872.3690	The subject device is regulated the same as K093708, K151764, and K132937.
Product Code	EBG	EBG	1. EBG 2. EBG 3. EBF	
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	For the fabrication of temporary crowns and bridges using the CAD/CAM technology until the permanent restoration can be delivered.		Same.

	restorations can be delivered. Restorations are designed and manufactured by dental professionals and technicians using open CAD/CAM technology.			
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	PMMA, pigments	The subject device is composed of the same or similar materials used in the predicate and reference devices.
Biocompatibility	Biocompatible	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		Same.

5.7: Statement of Substantial Equivalence

The subject and predicate devices are similar in 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.