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

November 23, 2015

Yamahachi Dental Products USA, Inc.
c/o Mr. Claude Berthoin
Denterprise International, Inc.
100 East Granada Blvd., Suite 219
Ormand Beach, FL 32176

Re: K151764
Trade/Device Name: Yamahachi PMMA Disks
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Code: EBG
Dated: October 14, 2015
Received: October 16, 2015

Dear Mr. Berthoin:

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 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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K151764

Device Name
Yamahachi PMMA DISKS

Indications for Use *(Describe)*
YAMAHACHI PMMA DISKS 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.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

Submitter/Applicant

Yamahachi Dental Products USA, Inc.
160 Park Avenue
Nutley, NJ 07110

Phone: 973-320-2909
Fax: 973-320-2995
Contact: Lawrence G. Greenwald (Yamahachi1@yahoo.com)
Date Prepared: June 23, 2015

Preparer/Consultant

Denterprise International, Inc.
100 East Granada Blvd., Suite 219
Ormond Beach, FL 32176

Phone: 386-672-0450
eFax: 855-235-7902
Contact Person: Joyce St. Germain, Regulatory Executive

Device Classification

Trade Name:	Yamahachi PMMA Disks
Common Name:	PMMA Disks
Classification Name:	Temporary Crown and Bridge Resin
Regulation Number:	21 CFR 872.3770 Class II
Product Code:	EBG

Predicate Device

The subject device claims equivalence to the following legally marketed predicate:

510(k) Number:	K093708
Trade Name:	Telio CAD
Manufacturer:	Ivoclar Vivadent, Inc. (Amherst, NY, USA)
Regulation Number:	21 CFR 872.3770
Product Code:	EBG

Indictions for Use

YAMAHACHI PMMA DISKS 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.

Device Description

Yamahachi PMMA Disks are acrylic blanks used in dental CAD/CAM milling systems by professional dental technicians to fabricate temporary crowns and bridges. After polishing, the prosthesis is adjusted in the patient's mouth and cemented or bonded in place, where it remains until removal when the permanent restoration is available.

The restoration process begins in the dental office with an intraoral scan of the affected tooth and the surrounding teeth. Proprietary software takes this digital image and creates a replacement part for the missing areas of the tooth, creating a virtual restoration. The software sends this virtual data to a milling machine where the replacement part is carved out of a Yamahachi PMMA Disk. The optical impression system, software, and milling machine are not part of the device.

The device is composed of hot-cured polymethyl methacrylate (PMMA) and pigments.

Yamahachi PMMA Disks are available in different shapes and shades, with disks of all shades available in different dimensions (diameter, thickness and profile margin). It is intended for use in both open and closed CAD/CAM systems. The circular disk model fits open milling systems, while the configurations for closed systems include Amann Girrbach, Zirkonzahn, block, pin and 2-pin.

Comparison of Technological Characteristics with Predicate

The following table compares technological and other characteristics of the subject and predicate device.

Table 5 -- Technological Comparison

	Subject Device	Predicate Device	Comparison
Device	**PMMA Disk**	**Telio CAD**	**NA**
510(k) Owner	Yamahachi Dental Products (USA)	Ivoclar Vivadent (Germany)	NA
Classification & Product Code	872.3770; EBG	872.3770; EBG	Same
Device Description	Temporary Crown And Bridge Resin	Temporary Crown And Bridge Resin	Same
Common Name	PMMA Disk	PMMA Disk	Same
Intended Use	Milling blanks for fabrication of long-term temporary crowns & bridges in CAD/CAM systems.	Milling blanks for fabrication of long-term temporary crowns & bridges in CAD/CAM systems.	Same

Indication For Use	YAMAHACHI PMMA DISKS 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.	For the fabrication of temporary crowns and bridges using CAD/CAM technology until permanent restoration can be delivered.	Same

Technological Characteristics

Product State	Solid	Solid	Same
How Device Is Made	Powder + Liquid methacrylate-based resins mixed together and heat cured	Powder + Liquid methacrylate-based resins mixed together and heat cured	Same
General Description	Cross-linked PMMA-based resins with pigments for tinting	Cross-linked PMMA-based resins with pigments for tinting	Same
Configurations	Open--Disc; Closed--Amann Girrbach, Zirkonzahn, Block, Pin & 2 Pin	Closed--Block, Disc	Subject used in open as well as closed systems; not a meaningful difference.
Components	PMMA with cross-linker and pigments	PMMA with cross-linker and pigments	Same

Non-clinical Performance testing

Physical Properties	ISO 10477:2004 Met acceptance criteria of this standard.	ISO 10477:2004	Same
Classification (ISO 10477)	Type 2, Class 1 (Heat Cure Without Photo-Sensitive Initiator)	Type 2, Class 1 (Heat Cure Without Photo-Sensitive Initiator)	Same
Shelf Life	10 Years	Not determined	Subject exceeds practical shelf life

The above comparison shows the subject and predicate devices have substantially similar technology characteristics.

Conclusion

The nonclinical tests demonstrate that the device is substantially equivalent to predicate device since they have the same intended use, material composition, and performed as well in physical properties testing; therefore, Yamahachi PMMA Disks warrants a finding of substantial equivalence to the legally marketed predicate device.