Yamahachi Dental Mfg., Co.
% Joyce St. Germain/Claude Berthoin
Regulatory Dept. Manager/CEO
Denterprise International, Inc./510k FDA Consulting
100 East Granada Blvd.
Ormond Beach Florida 32176

January 16, 2018

Re: K172683
Trade/Device Name: Yamahachi Pink CAD/CAM Disk
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture relining, repairing, or rebasing resin
Regulatory Class: Class II
Product Code: EBI
Dated: December 4, 2017
Received: December 7, 2017

Dear Joyce St. Germain/Claude 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.

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.

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

forTina 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)*

Device Name
Yamahachi Pink CAD/CAM Disk

Indications for Use *(Describe)*
Yamahachi Pink CAD/CAM Disk is used for the fabrication 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.

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510k FDA Consulting

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510(k) Summary

Submitter/Applicant K172683

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Date Prepared: August 30, 2017

Preparer/Consultant

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Primary Contact: Joyce St. Germain, Regulatory Dept Manager, joyce@510kfda.com
Secondary Contact: Claude Berthoin, CEO, claude@denterpriseintl.com

Device Classification

Trade Name: Yamahachi Pink CAD/CAM Disk
Common Name: Pink CAD/CAM Disk
Classification Name: Denture relining, repairing, or rebasing resin
Regulation Number: 21 CFR 872.3760
Product Code: EBI
Class: 2

Predicate Device

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

510(k) Number:	K153546
Trade Name:	Pink CAD/CAM Disc
Manufacturer:	Polident D.O.O.
Regulation Number:	21 CFR 872.3760
Product Code:	EBI

Reference Predicate Device

The following reference is a legally marketed, post-amendment device. This reference predicate is the same PMMA Disk (only the shade is different) and the same CAD/CAM system cleared that is used with the subject device.

510(k) Number:	K151764
Clearance Date:	November 23, 2015
Trade Name:	Yamahachi PMMA Disk
Manufacturer:	Yamahachi Dental Material Co., Ltd., China
Regulation & PC:	872.3770; EBG

Reference Predicate Device

The following reference is a legally marketed, post-amendment device. This reference predicate is identical chemical composition as the subject device made and cleared by Yamahachi with Resin Basis and Basis Hi devices.

510(k) Number:	K131036
Clearance Date:	July 12, 2013
Trade Name:	Yamahachi Denture Base Resins
Manufacturer:	Yamahachi Dental Mfg., Co., Japan
Regulation & PC:	872.3760; EBI

Indications for Use

YAMAHACHI Pink CAD/CAM Disk is used for the fabrication of dentures.

Intended Use

PMMA Disks are polymethyl methacrylate blanks used to mill dentures in various CAD/CAM systems.

Device Description

Yamahachi PMMA Disks are acrylic blanks used in dental CAD/CAM milling systems by professional dental technicians to fabricate dentures. 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 included in this submission.

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

Yamahachi Pink 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, closed and block type CAD/CAM systems. The circular disk model fits open milling systems, while the configurations for closed systems include Amann Girrbach, Zirkonzahn and block type can be used for any milling machine with the appropriate and compatible CAM system.

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	**Pink Disk**	**Pink CAD/CAM Disc**	**NA**
K number	**K172683**	**K153546**	**NA**
510(k) Owner	Yamahachi Dental Mfg., Co. (Japan)	Polident D.O.O.	NA
Classification & Product Code	872.3760; EBI	872.3760; EBI	Same
Classification Name	Denture relining, repairing, or rebasing resin	Denture relining, repairing, or rebasing resin	Same
Common Name	PMMA CAD/CAM Disk	PMMA CAD/CAM Disk	Same
Device Description	Disks are milling blanks used in the fabrication of dentures.	Disks are milling blanks used in the fabrication of dentures	Same
Intended Use	PMMA Disks are polymethyl methacrylate blanks used to mill dentures in various CAD/CAM	Fabrication of dentures.	Same

	systems.		
Indication For Use	YAMAHACHI Pink CAD/CAM Disk is used in the fabrication of dentures.	Fabrication of dentures.	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
Fabrication	CAD/CAM technique	CAD/CAM technique	Same
General Description	Cross-linked PMMA-based resins with pigments for tinting	Cross-linked PMMA-based resins with pigments for tinting	Same
Configurations	Open--Disk; Closed--Amann Girrbach, Zirkonzahn, Block, Pin & 2 Pin	Closed and Block Disc	Same Subject also available for open disk use.
Components	PMMA with cross-linker and pigments	PMMA with cross-linker and pigments	Same
Biocompatibility	Previously tested and established with FDA with cleared device K131036	Predicate Biocompatibility complete for device clearance	Same

Non-clinical Performance testing

Physical Properties	ISO 10477:2004 Met acceptance criteria of this standard.	ISO 10477:2004	Same
Shelf Life	10 Years	Not determined	Subject exceeds practical shelf life

ADDITIONAL: ISO 20795-1:2013 Dentistry – Denture base polymers. The subject device was also tested on the following according to the standard:

- Appearance
- Size/Diameter (minimum to maximum)
- Thickness (minimum to maximum)
- Color of Shades
- Flexural Strength
- Flexural Modulus
- Water Sorption
- Solubility
- Color Stability
- Translucency
- Residual MMA

Substantial Equivalence

The above comparison chart shows the subject and predicate devices are substantially equivalent in technological characteristics.

The subject and predicate devices have the same material composition of PMMA Disks composed of polymethyl methacrylate, hot cured polymer.

The subject and predicate have the same function and the same intended use to fabricate the final products by CAD/CAM technique and have similar physical and chemical properties.

The subject and predicate are manufactured under the same technological process with the same raw material used.

The subject and predicate have both completed ISO standardized testing and have passed and the tests are in the comparison chart shown above.

Conclusion

The nonclinical tests demonstrate that the device is substantially equivalent to the predicate device since they have the same intended use, material composition, and performed as well in the physical properties testing. Therefore, Yamahachi Pink CAD/CAM Disk demonstrates that it is as safe, as effective, and performs as well as the predicate device and warrants a finding of substantial equivalence to the legally marketed predicate device.