DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 13, 2015

Ivoclar Vivadent, Incorporated
Donna Marie Hartnett, Esq.
Director QA/Regulatory Affairs
175 Pineview Drive
Amherst, New York 14228

Re: K151142
Trade/Device Name: IvoBase CAD for Zenotec, IvoBase CAD Bond, and Modelling Liquid
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Codes: EBI, MQC
Dated: May 19, 2015
Received: May 20, 2015

Dear Ms. Hartnett:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Erin I. Keith -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151142

Device Name
IvoBase CAD for Zenotec, IvoBase CAD Bond and Modelling Liquid

Indications for Use *(Describe)*
IvoBase CAD for Zenotec, IvoBase CAD Bond and Modelling Liquid is a system used:
For the fabrication of removable dentures,e.g.:

- partial and complete denture prosthetics
- hybrid denture prosthetics
- combined denture prosthetics
- mouthguards
- implant-supported denture prosthetics

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)

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510(K) SUMMARY

(Revised 8.12.15)
IvoBase CAD for Zenotec and
IvoBase CAD Bond and Modelling Liquid

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Date Prepared: August 12, 2015

Proprietary Name: **IvoBase CAD for Zenotec and**
IvoBase CAD Bond and Modelling Liquid

Classification Name: Resin, Denture, Relining, repairing, rebasing (872.3760) – Class II
Classification Code EBI

Predicate Devices: IvoBase CAD for Zenotec is substantially equivalent to:
(Primary Predicate) - M-PM-Disc (Pink) (K140758) marketed by Merz Dental GmbH.
- SR Ivocap Plus (K915377) manufactured by Ivoclar Vivadent, AG
- Probase Hot and Cold (K913655)
- Ivobase Hybrid, Ivobase High Impact (K103391)
both manufactured by Ivoclar Vivadent, AG.

Device Description: IvoBase CAD for Zenotec is presented as a system including a ready-to-use industrially polymerized disc made primarily from PMMA. The denture base disc is milled using the CAD/CAM technique to form the base of a partial, full denture or mouthguard. Commercially available preformed denture teeth are then bonded to the denture base using IvoBase CAD Bond and IvoBase CAD Modelling Liquid.

Traditionally dentures have been made by preparing a dough from polymer powder and monomer liquid which is then polymerized using heat. The new aspect of IvoBase CAD for Zenotec is that this dough is industrially polymerized and ready-to-use for the dental technician. CAD/CAM technology is used to design and mill the denture instead of preparing a model and using the lost-wax technique.

The advantage of the new working technique is that polymerization shrinkage has already taken place and therefore the accuracy of the denture can be expected to be improved. Additionally, the dental technician can use the CAD/CAM technique which is now routine for dental laboratory procedures. Because the end prosthesis is the same as one created using historic

lost-wax technique, there are no new issues of safety and effectiveness created by the device which is the subject of this submission.

Intended Use:
IvoBase CAD for Zenotec, IvoBase CAD Bond and Modelling Liquid is a system used:
For the fabrication of removable dentures,e.g.:

- partial and complete denture prosthetics
- hybrid denture prosthetics
- combined denture prosthetics
- mouthguards
- implant-supported denture prosthetics

Comparison to predicate

	Predicate Device M-PM-Disc (Pink) (K140758) (unless otherwise noted)	Subject Device
Indications	M-PM-Disc (Pink) (K140758) Device for fabrication of dental bases for removable dentures. Ivocap High Impact (K915377) is used for: - Complete dentures - Partial dentures - Bases and relines - Orthodontic appliances - Bite guard splints	IvoBase CAD for Zenotec is used for the fabrication of: - Partial and complete denture prosthetics - Combined denture prosthetics - Implant-supported prosthetics - Hybrid prosthetics - Mouthguards
CAD CAM Technology	M-PM-Disc (Pink) (k140758) - pink PMMA disc intended for use in the fabrication of denture bases using CAD CAM technology	IvoBase CAD for Zenotec is a PMMA disc intended for use in the fabrication of denture prosthetics using CAD CAM Technology.
Monomer/polymer form	M-PM-Disc (Pink) (K140758) PMMA material in disc form with denture formed using CAD CAM Technology. IvoBase Hybrid, IvoBase High Impact (K103391) is presented as a polymer powder and monomer liquid which are sold in pre-dosed capsules. The material is automatically mixed using the appropriate equipment (Ivocap machine). The mixed acrylic is injected into the prepared form containing the prosthetic denture teeth. The material is polymerized using heat. Final adjustments are then made.	The denture base is formed using CAD CAM technology. The prosthetic denture teeth are then bonded to the denture base using IvoBase CAD Bond and IvoBase CAD Modelling Liquid. IvoBase CAD Bond consists of a powder polymer and monomer liquid similar to a traditional denture base device.

Principles of operation	**Step-by-step:** - Anatomical impression - Lab makes plaster model and individual tray - Impression and bite registration - Lab makes plaster master model and wax try-in - Try-in and functional check - Lab sets teeth, embeds in mold, boils out wax and replaces with denture base resin. - After curing final adjustments and polishing - Insertion	**Step-by-step:** - Anatomical impression and pre-bite registration - Lab makes scan of impression and mills individual tray - Functional impression and bite registration - Lab makes scan and mills try-in body (Tray Disc for Zenotec) - Try-in and esthetic, functional check - Lab makes final denture. IvoBase CAD for Zenotec can be processed using the Zenotec select milling machine. First the lingual side is milled, then the teeth are bonded in position using ivoBase CAD Bond and then the basal side is milled. - After milling, the denture base is separated from the disc, shape adjustments are made and then it is polished. - Insertion
Composition	Traditional PMMA Polymer/monomer denture base material with pigmentation for shade	The chemical composition of the new product and predicate are the same, except for small changes in pigments and the fact that the disc product is industrially polymerized. Therefore certain ingredients (the methyl methacrylate and initiators) are no longer present. The result of the biocompatibility assessment is that the product is equivalent to the predicate.

The comparison shows that **IvoBase CAD for Zenotec and IvoBase CAD Bond and Modelling Liquid** is substantially equivalent to the predicate device.

Technological Characteristics: The basic process for the dentist remains the same however the dental technician mills the denture using CAD/CAM technology instead of using the lost-wax technique. The product is supplied as a polymerized disc instead of powder/liquid to be mixed and cured. The bonding process of the denture teeth is new as traditionally denture teeth are set using a heat or self curing process after mixing a powder and monomer liquid into a dough. The finished device is intended to operate the same as the predicate.

Testing Summary:

- EN ISO 20795-1:2013 Dentistry – Base Polymers Part 1: Denture base polymers (ISO 20795-1:2013) does not directly apply because the scope of this standard covers

powder and liquid material which are mixed together and polymerized. IvoBase CAD for Zenotec is supplied as a ready-to-use disc which has been industrially polymerized. However this standard contains elements which are relevant for the verification of IvoBase CAD for Zenotec and the material was tested in accordance with EN ISO 20795:2013 for Ultimate flexural strength, Flexural modulus, Maximum stress intensity factor, Total fracture work, Residual MMA, Water sorption (7 days), and Solubility (7 days).

- IvoBase Bond materials were tested for water sorption and solubility and found to be comparable with the predicate device Probase Cold (K913655).
- The quality of the bonding of synthetic polymer denture teeth to IvoBase CAD for Zenotec using IvoBase CAD Bond was tested in accordance with EN ISO 22112:2005 Dentistry: Artificial Teeth for dental prosthesis and a cohesive fracture was verified.
- When compared to the predicate device, the physical properties and bonding of the subject device are substantially equivalent.

Biocompatibility:

- Biocompatibility testing and evaluation was carried out according to ISO 10993 and ISO 7405 for Dentistry.
- The polymerized disc and Bond materials were tested for cytotoxicity and genotoxicity and the results showed no cytotoxic or genotoxic results.
- Subchronic systemic toxicity testing was not conducted due to the low water solubility of the subject device.
- Irritation and sensitization risks were evaluated and found to be low, based on comparison to comparable devices.
- The chemical composition of the new product and predicate are the same, except for small changes in pigments and the fact that the disc product is industrially polymerized. Therefore certain ingredients (the methyl methacrylate and initiators) are no longer present.
- The result of the biocompatibility assessment is that the subject device is equivalent to the predicate.

CONCLUSION: The above data and analysis demonstrates that **IvoBase CAD for Zenotec and IvoBase CAD Bond and Modelling Liquid** is substantially equivalent to the predicate device.