.RTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Polident D.O.O., Dental Products Industry
Janja Lipuscek
Head of Organic Programme
Volcja Draga 42
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September 28, 2016

Re: K153546
Trade/Device Name: Pink Cad/cam Disc
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI,
Dated: June 24, 2016
Received: July 7, 2016

Dear Janja Lipuscek:

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" (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 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,

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)*
K153546

Device Name
PINK CAD/CAM disc

Indications for Use *(Describe)*

- 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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Title 5: 510(k) Summary

510(k) owner`s name:	Polident d.o.o. Dental Products Industry Volčja Draga 42 5293 Volčja Draga Slovenija Phone: 00386-53304840 Fax: 00386-53304870
Contact person:	mag. Janja Lipušček Phone: 00386-53304859 e-mail: janja.lipuscek@polident.si
Date of summary:	21st September, 2016
Trade name:	**PINK CAD/CAM DISC**
Classification name:	Denture relining, repairing, or rebasing resin
Product codes:	EBI
Regulation number:	21 CFR 872.3760
Device class:	II
Predicate device:	M-PM-Disc (Pink) Producer: Merz Dental GmbH 510 (k) Number: K140758
Reference device:	PMMA CAD/CAM disc Producer: Polident d.o.o. 510 (k) Number: K112967

Device description:
PINK CAD/CAM disc are blanks used in different milling machines (dental CAD-CAM systems) by professional dental technicians.
They are composed of hot cured polymethyl methacrylate (PMMA) and pigments. Device is available in different pink shades. Discs of all shades are available in different dimensions (diameter, thickness and profile margin).

Indications for use:
- Fabrication of dentures

Summary of the technological characteristics compared to the predicate devices:

	Device: **PINK CAD/CAM disc**	Predicate device: **M-PM-Disc (Pink)**	Reference device: **PMMA CAD/CAM disc**
Form	Solid disc	Solid disc *(the same)*	Solid disc *(the same)*
Shades	Denture base coloured shade	Denture base coloured shade *(the same)*	Tooth coloured shade
Composition	Hot cured cross-linked polymethyl methacrylate	Hot cured cross-linked polymethyl methacrylate *(the same)*	Hot cured cross-linked polymethyl methacrylate *(the same)*
Material used	Polident PMMA CAD/CAM disc material	OMP-N PMMA material	Polident PMMA CAD/CAM disc material *(the same)*
Manufacturer`s technological process used	Polident PMMA CAD/CAM disc process	Merz Dental process	Polident PMMA CAD/CAM disc process *(the same)*
Fabrication	CAD/CAM technique	CAD/CAM technique *(the same)*	CAD/CAM technique *(the same)*
Indications for use	Fabrication of dentures	Fabrication of dentures *(the same)*	Fabrication of temporary crowns and bridges
E-modulus (MPa) /EN ISO 20795-1/	3040	2678 *(the same)*	2771 *(the same)*
Fluxural strenght(MPa) /EN ISO 20795-1/	115,8	90 *(the same)*	114 *(the same)*
Residual methyl methacrylate (%) /EN ISO 20795-1/	1,02	1,14 *(the same)*	1,02 *(the same)*
Biocompatibility: cytotoxicity test /EN ISO 10993-5/	Met the requirements of EN ISO 10993-5	Met the requirements of EN ISO 10993-5 *(the same)*	Met the requirements of EN ISO 10993-5 *(the same)*
Biocompatibility: irritation test /EN ISO 10993-10/	Met the requirements of EN ISO 10993-10	Test has not been performed	Met the requirements of EN ISO 10993-10 *(the same)*
Biocompatibility: sensitization test /EN ISO 10993-10/	Met the requirements of EN ISO 10993-10	Met the requirements of EN ISO 10993-10 *(the same)*	Met the requirements of EN ISO 10993-10 *(the same)*

Substantial equivalence:

The proposed device PINK CAD/CAM disc, predicate device M-PM-Disc (Pink) and reference device PMMA CAD/CAM disc are composed of polymethyl methacrylate hot cured polymer. All three devices have the same aesthetic function and are intended to fabricate the final products by CAD/CAM technique and have similar physical and chemical properties. The polymerization grade of all devices is high.

The proposed device and predicate device M-PM-Disc (Pink) have the same indication for use and are available in pink shades.

The proposed device and reference device PMMA CAD/CAM disc are composed of the same material type and are manufactured under the same technological process with the same raw material used. The material is called Polident PMMA CAD/CAM disc material. As is evident from the table, some tests have been performed with Polident PMMA CAD/CAM disc material used for fabrication of proposed device PINK CAD/CAM disc and reference device PMMA CAD/CAM disc. The performance characteristics have been determinated with PINK CAD/CAM disc. The same tests have been performed also with OMP-N PMMA material used for predicate device M-PM-Disc (Pink).
The test results of E-modulus and flexural strength have been obtained with PINK CAD/CAM disc. The requirements of standard EN ISO 20795-1:2008: Dentistry- Base polymers –Part 1: Denture base polymers are that the required E-modulus of Type 1 material must be minimum 2000 MPa and required fluxural strength minimum 65 MPa. Both devices- PINK CAD/CAM disc and M-PM-Disc (Pink) comply with the requirements of standard EN ISO 20795-1 regarding the required flexural properties. The residual methyl methacrylate content of disc polymerised by Polident PMMA CAD/CAM disc material has been determined with regard to standard EN ISO 20795-1:2008: Dentistry- Base polymers –Part 1: Denture base polymers. The measured value is 1,02 wt-%. The requirement of residual monomer content with regard to EN ISO 20795-1 for Type 1 material is 2,2 wt-%. So PINK CAD/CAM disc complies the requirement of residual menthyl methacrylate content. In the literature company Merz Dental, the producer of predicate device M-PM-Disc (Pink), published that the amount of residual monomer in M-PM-Disc is 1,14 wt-%.

Therefore also cytotoxicity, sensitization and irritation testing was conducted on reference device PMMA CAD/CAM disc composed of Polident PMMA CAD/CAM disc material. The test results are that PMMA CAD/CAM disc material used for fabrication of reference device PMMA CAD/CAM disc and proposed device PINK CAD/CAM disc complies with the requirements of standard EN ISO 10993 regarding cytotoxicity, irritation and sensitization properties. The Certificate of Compliance with ISO 10993: Biological Evaluation of Medical Devices for PMMA CAD/CAM disc has been issued.

We can conclude that the proposed device PINK CAD/CAM DISC has comparible technological characteristics to the predicate device. The device beeing considered to be substantially equivalent in safety and effectiveness to the predicate device.

Conclusion:
We are claimed substantial equivalence of PINK CAD/CAM DISC to the predicate device.