Dental Direkt GmbH
Patrick Berz
Regulatory Affairs Manager
Industriezentrum 106-108
Spenge, 32139
Germany

Re: K230410
Trade/Device Name: DD medical polymers (PMMA)
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI, MQC
Dated: May 25, 2023
Received: May 25, 2023

Dear Patrick Berz:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M. ChE., CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K230410

Device Name

DD medical polymers (PMMA)

Indications for Use *(Describe)*

DD base P HI are pre-colored dental milling blanks made of impact-resistant PMMA for the manufacture of denture bases for removable dentures. DD base P HI is suitable for long-term use in the oral cavity up to 10 years.

DD Bio Splint P HI are transparent dental milling blanks out of PMMA for the manufacture of splints, therapeutic splints and bite regulators for long-term application in the oral cavity up to 12 months.

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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510(k) Summary

as required by 21 CFR 807.92(c)

510(k) Number: K230410

Date: 2023/05/25

510(k) Summary

Submitter of 510(k)	Dental Direkt GmbH Industriezentrum 106-108 32139 Spenge / Germany
Contact Person	Patrick Berz, Manager Regulatory Affairs Phone: +49 5225 86319-0 Fax: +49 5225 86319-99 p.berz@dentaldirekt.de
Establishment Registration No.	3008347275
Date Prepared	2023/05/25
Trade Name of Device	DD medical polymers (PMMA)
Classification Product Code	EBI
Subsequent Product Codes	MQC
Common Name	Resin, Denture, Relining, Repairing, Rebasing
Regulation Number	21 CFR 872.3760
Panel	Dental
Classification	Class II
Primary Predicate Device	K153490: Dental Direkt GmbH DD medical polymers
Reference Device	K150432 Union Dental S.A. IDODENTINE DISC

Indications for Use

DD Bio Splint P HI are transparent dental milling blanks out of PMMA for the manufacture of splints, therapeutic splints and bite regulators for long-term application in the oral cavity up to 12 months.

DD base P HI are pre-colored dental milling blanks made of impact-resistant PMMA for the manufacture of denture bases for removable dentures. DD base P HI is suitable for long-term use in the oral cavity up to 10 years.

Device Description

DD medical polymers (PMMA), made from PMMA, are industrially polymerized, pre-colored or clear dental milling blanks designed for milled fabrication of bite splints (clear variant) or denture bases (gingiva-colored variants) on dental CAD/CAM systems.

Technological Characteristics

The technological characteristics of the modified device are comparable to the legally marketed device. The physical properties are not identical to the Predicate Device but can be considered as sufficient, since the values meet the requirements of the relevant standards ISO 20795-1 and ISO 20795-2 as well as the values of the Predicate Device / Reference Device.
All devices are made of PMMA, partly with small amounts of coloring pigments.

Material

PMMA

Discussion of Tests Performed

Clinical Tests
Dental Direkt GmbH did not conduct, nor rely upon, clinical tests to determine substantial equivalence as dental polymers that fall under the FDA product codes MQC and EBI have a long history of safe and effective use in the US.

Non Clinical Tests
Non-clinical testing was performed in order to validate the product against the company's specified design requirements according to the following standards:

- EN ISO 10993-1 (biological compatibility) and EN ISO 10993-5 (cytotoxicity)

DD medical polymers (PMMA) were tested by an accredited testing laboratory with respect to biocompatibility. Based on the test results DD medical polymers was classified as eminently suitable for use in the dental applications.

- ISO 20795-1, Dentistry – Base polymers - Part 1: Denture base polymers (FDA Recognition # 4-232)

- ISO 20795-2, Dentistry – Base polymers – Part 2: Orthodontic base polymers (FDA Recognition # 4-233)

Feature	New Device	Primary Predicate Device	Reference Device	Comment
Trade name	DD medical polymers (PMMA)	DD medical polymers	IDODENTINE DISC	n.a.
Included products	DD base P HI DD Bio Splint P HI	DD temp MED DD Bio Splint P	n.a.	n.a.
510(k)	K230410	K153490	K150432	n.a.
Product codes	EBI (DD base P HI)	n.a.	EBI	Identical to Reference Device
	MQC (DD Bio Splint P HI)	MQC (DD Bio Splint P)	MQC	Identical
	n.a.	EBG (DD temp MED)	EBG	n.a. (Not part of this submission)
Regulatory class	Class II	Class II	Class II	Identical
Manufacturer	Dental Direkt GmbH	Dental Direkt GmbH	Union Dental S.A.	n.a.
Intended use	DD base P HI are pre-colored dental milling blanks made of impact-resistant PMMA for the manufacture of denture bases for removable dentures. DD base P HI is suitable for long-term use in the oral cavity up to 10 years. DD Bio Splint P HI are transparent dental milling blanks out of PMMA for the manufacture of splints, therapeutic splints and bite regulators for long-term application in the oral cavity up to 12 months.	DD medical polymers are indicated for temporary (≤ 12 months) crowns, bridges and bite splints. Applications include both anterior and posterior structures.	Acrylic polymer blank particularly suitable for maling removable or temporary dental structures such as crowns and bridges using milling technology using CAD/CAM. Indications: - Temporary anterior and posterior crowns - Temporary anterior and posterior bridges with up to two adjacent pontics - Implant supported temporary restorations Maximum recommen-ded usage period: 12 months	DD Bio Splint P HI: Identical to Predicate Device DD base P HI: Identical to Reference Device: - different wording, but identical (both suitable for removable denture bases) - wording of Reference Device is much more general (see discussion)

Feature	New Device	Primary Predicate Device	Reference Device	Comment
			- Removable structures for dentures (dental bases) - Removable structures for therapeutic restorations (bite splints or occlusal splints)	
Max. application	12 months (DD Bio Splint P HI)	12 months	12 months	Identical to Predicate Device
	10 years (DD base P HI)		Not restricted	Comparable to Reference Device, see discussion
Technology	Blank for dental CAD/CAM machining	Blank for dental CAD/CAM machining	Blank for dental CAD/CAM machining	Identical
Shape	Disc	Disc	Disc	Identical
Shade	clear, pink	VITA-shades, clear	VITA shades, clear, pink	Identical
Raw material	PMMA	PMMA	PMMA	Identical
	Chemical composition [Units]			
Material base	> 99.0 [wt%] (Polymethyl methacrylate)	> 99.0 [wt%] (Polymethyl methacrylate)	Polymethyl methacrylate	Identical to Predicate Device
Coloring pigments	≤ 1.0 [wt%]	≤ 1.0 [wt%]	Not specified	Identical to Predicate Device

Feature	New Device	Primary Predicate Device	Reference Device	Comment
	Physical characteristics [Units]			
Flexural strength	≥ 64 MPa	≥ 75 MPa	90 MPa	Comparable (see discussion)
Flexural modulus	≤ 2030 MPa	2800 (± 200) MPa	*Not stated in 510(k) submission*	Comparable (see discussion)
Water absorbtion	< 24 µg/mm³	≤ 23 µg/mm³	< 23 µg/mm³	Comparable (see discussion)
Solubility	< 0.3 µg/mm³	0.2 µg/mm³	< 0.0 µg/mm³	Comparable (see discussion)
Residual monomer content	< 0.7 %	0.4 %	< 1.4 %	Comparable (see discussion)
Stress intensity factor	≥ 2.4 MPa*$m^{1/2}$ (DD base P HI)	*Not stated in 510(k) submission*	*Not stated in 510(k) submission*	See discussion
Fracture work	> 2200 J/m² (DD base P HI)	*Not stated in 510(k) submission*	*Not stated in 510(k) submission*	See discussion
Physical tests according to:	ISO 10477 (only relevant excerpts), ISO 20795-1, ISO 20795-2	ISO 10477, ISO 20795-1	ISO 10477, ISO 20795-1	Comparable (see discussion)
Biocompatibilty tests according to:	EN ISO 10993-1, -5	EN ISO 10993-1, -5	EN ISO 10993-1, -5	Identical

Substantial Equivalence Discussion / Conclusion

The goal of this submission is to add additional products to the already approved DD medical polymers product group.
The maximum application time, the product codes and the shade of DD Bio Splint P HI are the same compared to the Predicate Device. Only DD base P HI differs slightly from the Predicate Device. Therefore, the Reference Device was added to the table above.

While DD Bio Splint P HI represents a further development of the product DD Bio Splint P which is included in the Predicate Device, the product DD base P HI extends the field of application to denture bases. Therefore, the Intended Use was adjusted and a new product code (EBI) was added. The

Intended Use of DD Bio Splint P HI is identical to the Intended Use of the Predicate Device, even though the wording is not exactly the same. This is because the Intended Use of the Predicate Device is more detailed compared to the general Intended Use of the Predicate Device.

The Intended Use of DD base P HI is identical to that of the Reference Device, even though there is a slightly different wording. The Intended Use of the Reference Device is much more general; however, the Intended Use of the Subject Device falls under the Intended Use of the Reference Device (both suitable for denture bases). The application time in the Intended Use of the Reference Device is not restricted, while Dental Direkt restricts the application time to 10 years. Since a longer application time leads to a higher risk, the application time of 10 years is less risky and therefore falls under the application time of the Reference Device.
Theoretically, the material is suitable for a longer application time; however Dental Direkt has conducted an accelerated aging test where over 10 years were simulated. Even after aging, no abnormalities were found in regard to biocompatibility. Nevertheless, Dental Direkt restricts the max. application time to 10 years.
Although the indication was extended to denture bases compared to the Predicate Device, this does not pose an increased risk because the existing indication with crowns and bridges is surgically invasive and therefore more risky than denture bases. Denture bases are only invasive, because they only lie on the oral mucosa.

Compared to the Predicate Device, new shades were added. The base material PMMA is the same for all products of DD medical polymers, only different amounts of coloring pigments were chosen to simulate the gingival color. Biocompatibility tests according ISO 10993-1 and ISO 10993-5 were conducted and the results show no cytotoxical potential. The available shades are identical to those of the Reference Device and, in case of DD Bio Splint P HI, to those of the Predicate Device as well.

The physical properties are not fully identical to those of the Predicate Device, but can be considered as comparable. In case of stress intensity factor and fracture work, both are not mentioned in the Predicate Device / Reference Device. However, since the raw material is the same and the values comply with the requirements of the relevant standards ISO 20795-1, ISO 20795-2 and the FDA Guidance *"Denture Base Resins – Performance Criteria for Safety and Performance Based Pathway: Guidance for Industry and Food and Drug Administration Staff"*, there is no increased risk.

All other features are identical to the Predicate Device / Reference Device.

Conclusion

Most product specifications and characteristics of the unmodified device are identical to the modified device / reference device. Product specification and characteristics (e.g. application time) have been tested and are shown in the risk analysis. All tests were passed.

This is why Dental Direkt GmbH believes that the modified product DD medical polymers (PMMA) is substantially equivalent to the legally marketed and unmodified device / reference device.