April 25, 2024

DWS s.r.l.
Anna Maria
Quality and Regulatory
Via della Meccanica 21
Thiene, Vicenza 36016
ITALY

Re: K231142
Trade/Device Name: Temporis, Irix Plus
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF, EBG
Dated: March 28, 2024
Received: March 28, 2024

Dear Anna Maria:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Michael E. Adjodha -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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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.

510(k) Number *(if known)*
K231142

Device Name
Temporis - Irix Plus

Indications for Use *(Describe)*
Temporis and Irix Plus are light-curing 3D-printing materials intended for fabricating indirect restorative for both anterior and posterior restorations, such as inlays, onlays, veneers, anterior or posterior crowns and bridges.
Temporis is used for fabricating temporary dental restorations, Irix Plus is used for fabricating permanent dental restorations.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary-K231142

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Date Summary Prepared:	March 28, 2024

DEVICE IDENTIFICATION

Trade name:	Temporis – Irix Plus
Generic/ Common Name:	Tooth Shade Resin Material
Regulation number:	21 CFR 872.3690 Class II
Regulation name:	Material, Tooth Shade, Resin
Product Code:	EBF, EBG
Panel:	Dental

PREDICATE DEVICES:

DWS identified the following legally marketed device as substantially equivalent:

TERA HARZ, Graphy Inc., K202846

DEVICE DESCRIPTION:

Temporis and Irix Plus are methacrylate-based resins used to manufacture high-precision three-dimensional custom-made dental restorations based on scanned images of the mouth of the patient. They are liquid resins that are subjected to solidification by laser induced polymerization - that is the process where monomers in liquid phase combine together to convert into polymers in solid phase - using dedicated 3D printing equipment working on the principle of stereolithography. The shape of the dental restoration is determined by a 3D stereolithographic drawing.

Temporis is used for manufacturing temporary dental restorations - such as inlays, onlays, veneers, anterior or posterior crowns and bridges (up to one pontic) - prior to the application of a permanent restoration. Irix Plus is used for manufacturing permanent dental restorations used to replace a decayed portion of tooth structure, like inlays, onlays, veneers, anterior or posterior crowns and bridges (up to one pontic).

INDICATIONS FOR USE:

Temporis and Irix Plus are light-curing 3D-printing materials intended for fabricating indirect restorative for both anterior and posterior restorations, such as inlays, onlays, veneers, anterior or posterior crowns and bridges.
Temporis is used for fabricating temporary dental restorations, Irix Plus is used for fabricating permanent dental restorations.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The side-by-side comparison between the subject and the predicate device shows that the devices have the same indications for use and are substantially equivalent in material composition and technological characteristics. The results of the tests performed show that the subject device meets the requirements mentioned in the applicable standards and confirm that the device performs similarly to predicate. Any differences between subject device and the predicate device are minimal and present no new risks. The noted differences, in comparison to the predicate device, raise no new questions of safety and effectiveness.

Feature	TEMPORIS – IRIX PLUS (Submitted Product)	PREDICATE DEVICE	CONCLUSION
K number	**K231142**	**K202846**	
Trade Name	Temporis, Irix Plus	TERA HARZ	
Manufacturer	D.W.S. S.r.l.	Graphy Inc.	
Regulation Number	21 CFR 872.3690	21 CFR 872.3690	same
Regulation Name	Tooth Shade Resin Material	Tooth Shade Resin Material	same
Regulatory Class	Class II	Class II	same
Product code	EBF, EBG	EBF, EBG	same
Indications For Use/Intended Use	Temporis and Irix Plus are light-curing 3D-printing materials intended for fabricating for both anterior and posterior restorations, such as inlays, onlays, veneers, anterior or posterior crowns and bridges. Temporis is used for fabricating temporary dental restorations, Irix Plus is intended used for fabricating permanent dental restorations.	TERA HARZ is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. The TERA HARZ material is used for fabricating temporary or permanent restorations such as crowns and bridges, inlays, onlays, veneers and full crown restorations. Fabrication of TERA HARZ requires a computer-aided and manufacturing (CAD/CAM) system that includes the following: scanner, design software, additive printer, and post-cure unit.	same Both the subject and predicate device are light-curing 3D-printing materials intended for the manufacturing of temporary or permanent anterior and posterior restorations
Intended Users	dentist or dental technician	dentist or dental technician	same
Material	Methacrylate-based resins.	Methacrylate-based resins.	substantially equivalent
Material Shades	Similar to Common VITA-shades	Common VITA-shades	substantially equivalent
Product State	Liquid	Liquid	same
Manufacturing Technology	3D liquid (light-cured) print resin for dental	3D liquid (light-cured) print resin for dental	same

Feature	TEMPORIS – IRIX PLUS (Submitted Product)	PREDICATE DEVICE	CONCLUSION
Sterility	Nonsterile	Nonsterile	same
Shelf Life	3 years	1 year	Different, however the results of the tests carried on the proposed device showed that the performance of the device after aging met the pre-determined acceptance criteria. Therefore, this difference will not raise new question on the safety and effectiveness of the proposed device.
Performance Testing	Performed tests according to ISO 4049:2019, Dentistry – Polymer-based restorative materials ISO 10477:2020, Dentistry –Polymer-based crown and veneering materials.	Performed tests according to ISO 4049:2013, Dentistry – Polymer-based restorative materials ISO 10477:2018, Dentistry – Polymer-based crown and veneering materials.	substantially equivalent The bench testing conducted on the subject device confirm that the minor differences in materials and technological characteristics do not affect the safety or effectiveness of the device and demonstrate that the subject device is substantially equivalent to the predicate device. No issues of safety or effectiveness arise.
Biocompatibility	Meet requirements for ISO 10993-1	Meet requirements for ISO 10993-1	substantially equivalent
OTC or Rx	Rx	Rx	same

The subject and predicate device share the same indications for use, they are both light-curing 3D-printing materials indicated as indirect restorative for anterior and posterior restorations.
The predicate device can be used for both temporary and permanent restorations just as the proposed resins Temporis and Irix Plus.
The materials used for the subject device are the same or similar to those used for the predicate device. Both the devices are methacrylate-based resins for 3D printing to be used to create a customized dental restoration. Methacrylate based resins are well known materials, commonly used in the dental industry for temporary and permanent dental restorations. The biocompatibility and performance testing show that slight differences in material composition do not raise any questions of safety or effectiveness; the subject device has demonstrated suitability for intended use through material non-clinical performance testing.
The proposed and predicate device are liquid photopolymers that are subjected to solidification by laser induced polymerization. Fabrication of the dental restorations requires for both the subject and the predicate device a computer-aided and manufacturing (CAD/CAM) system that includes the following: scanner, design software, additive printer, and post-cure unit.
The subject device has similar physical properties as the predicate device. The difference in the proposed shelf life will not raise new question on the new safety and effectiveness of the subject device as shown by the results of the stability testing performed.

SUBSTANTIAL EQUIVALENCE DISCUSSION:

DISCUSSION OF NONCLINICAL TESTS

Nonclinical tests were conducted to demonstrate substantial equivalence to the predicate device. The test results demonstrated that the proposed devices comply with the applicable sections of the standards listed below:

Biocompatibility:
The materials used to manufacture the subject device are the same/similar to those used for the predicate device. All the materials used to manufacture the subject device are largely used for other legally marketed devices under the same product code.

Biocompatibility has been assessed according to the requirements of
- ISO 10993-1:2018 *Biological evaluation of medical devices, Evaluation and testing within a risk management process.*
- ISO 7405:2018 *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*

The following biocompatibility tests were performed:
- Cytotoxicity, ISO 10993-5: 2009 *Biological evaluation of medical devices, Tests for in vitro cytotoxicity;*
- Oral mucosa irritation, *ISO 10993-23:2021 Biological evaluation of medical devices, Tests for irritation;*
- Skin Sensitization, *ISO 10993-10: 2010 Biological evaluation of medical devices, Tests for irritation and skin sensitization*;
- Acute Systemic Toxicity, *ISO 10993-11:2017 Biological evaluation of medical devices, Tests for systemic toxicity;*
- Subchronic Systemic Toxicity, *ISO 10993-11:2006 Biological evaluation of medical devices, Tests for systemic toxicity;*
- Genotoxicity, *ISO 10993-3:2014 Biological evaluation of medical devices, Tests for genotoxicity, carcinogenicity and reproductive toxicity.*

The subject device meets requirements for ISO 10993-1 as the predicate device.

Performance tests:
The proposed device was tested and met the applicable requirements per ISO 10477:2020 *Dentistry -Polymer-based crowns and veneering materials* and ISO 4049:2019, *Dentistry – Polymer-based restorative materials*.
The non-clinical tests performed confirmed that the minor differences in materials and technological characteristics in respect to the predicate device do not affect the safety or effectiveness of the proposed device.

CONCLUSION:

All the necessary safety and performance tests in support of substantial equivalence determination were conducted. The tests demonstrate that the subject Temporis and Irix Plus are safe, effective and performs as well as the predicate device. The minor differences between the devices do not raise any new issues of safety or efficacy.