August 16, 2022

Graphenano Dental S.L.
Maria Garcia
QA/RA Manager
C/ Pablo Casals , 13 Ba.
Yecla, Murcia 30510
SPAIN

Re: K220329
Trade/Device Name: G-CAM
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF, EBI, EBG
Dated: April 8, 2022
Received: June 17, 2022

Dear Maria Garcia:

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,

Michael E. Adjodha, M.ChE.
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.

510(k) Number *(if known)*
K220329

Device Name
G-CAM

Indications for Use *(Describe)*
G-CAM discs are intended to be used for the manufacture of full and partial removable dentures, implant overdentures as well as permanent and temporary restorations such as anterior or posterior crowns and bridges, inlays, onlays, veneers, copings and substructures.

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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K220329

SECTION 05 – 510(k) SUMMARY

I. SUBMITTER *(21 CFR 807.92(a)(1))*

DATE OF SUBMISSION: 2022-04-08
SUBMITTER NAME: Graphenano Dental S.L.
SUBMITTER ADDRESS: C/ Pablo Casals, 13 bajo.
30510 Yecla, Murcia
SPAIN
CONTACT PERSON: María Simón García, QA/RA Manager
TELEPHONE: +34 965 108 102
e-mail: mariasimon@graphenano.com

II. DEVICE *(21 CFR 807.92(a)(2))*

DEVICE TRADE NAME: G-CAM
COMMON NAME: Tooth Shade Resin Material
CLASSIFICATION NAME: Material, tooth shade, resin
REGULATION DESCRIPTION: Tooth Shade Resin Material
CLASS: Class II (Special Controls)
REGULATION NUMBER: 21 CFR 872.3690
PRODUCT CODE: EBF – Material, Tooth Shade, Resin
SUBSEQUENT PRODUCT CODES:
EBG – Crown and Bridge Temporary Resin
EBI – Denture Relining, Repairing, Rebasing Resin

III. PREDICATE DEVICE *(21 CFR 807.92(a)(3))*

Primary Predicate:

K160918	JUVORA Dental Disc

Reference Predicate:

K160425	CAD/CAMouflage Milling Block

IV. DEVICE DESCRIPTION *(21 CFR 807.92(a)(4))*

G-CAM is a thermoplastic acrylic disc made by a principal base of polymethyl methacrylate (PMMA) resin doped with graphene (allotropic form of carbon), suitable for the creation of dental prostheses using CAD/CAM technology.

G-CAM discs are intended to be used for the manufacture of full and partial removable dentures, implant overdentures as well as permanent and temporary restorations such as anterior or posterior crowns and bridges, inlays, onlays, veneers, copings and substructures.

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The previous indications for G-CAM are supported by the following concepts:

- G-CAM, polymethyl methacrylate (PMMA) doped with Graphene, is manufactured using the heat-curing method.
- G-CAM presents high modulus and elastic limit to ensure that the tensions generated during biting and chewing do not cause permanent deformations, and it is possible to manufacture prosthesis of smaller sections.
- G-CAM presents high deformation resistance and stress limit, thus avoiding the formation of cracks and fractures.
- G-CAM is low density making the prosthesis lightweight.
- G-CAM increases the material hardness comparing with acrylic resins used in dentistry.
- G-CAM final appearance is similar to oral tissue. Thus ideal for visible areas.
- G-CAM has colour stability.
- G-CAM has wide chromatic range, even within the same piece, making it look extremely natural.
- G-CAM disc is chemically inert.
- G-CAM water absorption is 4 µg/mm3 and a solubility of 0.5 µg/mm2. The release of residual monomer is minimum, with a percentage of 0.004% of residual monomer. Thanks to these physical properties G-CAM offers a durable and safety treatment.

G-CAM is available in different formats, thicknesses, colors and anchors, having all the variations the same physicochemical characteristics.

DEVICE DESING DESCRIPTION

The device is presented in a disc form which allow to process the dental prostheses with specific CAD /CAM equipment.

G-CAM disc is available in 2 different **formats**: G-CAM MONOCHROMA and G-CAM MULTICHROMA. Monochrome and Multichroma discs may be both used for anatomical monolithic restorations.

When machined, G-CAM Monochroma and G-CAM Multichroma present a different visual effect:

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- **G-CAM Monochroma**, is made of one pure VITA Classic guide's colour.
- **G-CAM Multichroma**, it has a chromatic spectrum based in natural colour imitating the optical effects of the natural pieces.

The more suitable choice between monochrome and multichrome disc will depend on the final application given to the device.

G-CAM is presented as a compacted resin disc offered in two different anchor dimensions.
There are two different discs variants base on the specified type of anchor used by the CAM device:

Universal anchorage: disc of 98.5mm diameter

Zirkonzahn anchorage: disc of 95mm diameter

Both variants are presented in different **thicknesses**: 14,16, 18, 20, 22, 24, 26, 28 and 30.

G-CAM device is available in the following **colours** TRANSPARENT, A1, A2, A3, A3.5, B1, B2, BL1, BL2, C2 and PINK (according to VITA classic guide).

G-CAM discs are provided non-sterile and as a single use device.
G-CAM must be used only by professionals as dental lab technicians and / or dentist.

G-CAM should be stored at room temperature in its original packaging, in dry storage and avoid exposure to direct sunlight. PMMA polymer from which the G-CAM disc is made is stable and can be stored for an extended period of time having a calculated 5-year shelf life (real-time testing method).

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V. INTENDED USE / INDICATIONS FOR USE *(21 CFR 807.92(a)(5))*

As established in the Indications for Use Statement:

"G-CAM discs are intended to be used for the manufacture of full and partial removable dentures, implant overdentures as well as permanent and temporary restorations such as anterior or posterior crowns and bridges, inlays, onlays, veneers, copings and substructures."

The primary predicate device, Juvora dental disc, and G-CAM, are classified under the same product codes: EBF – Material, Tooth Shade, Resin; EBG – Crown and Bridge Temporary Resin; EBI – *Denture* Relining, Repairing, Rebasing Resin. As can be seen in Table.1, below, the intended use of G-CAM and the Juvora dental disc is equivalent. Specifically, one indication of G-CAM is that is intended for final crowns and bridges, inlays, onlays and veneers restorations which means that can be used as a direct monolithic solution with no need of using other materials to make aesthetics restorations. Juvora dental disc is intended for frameworks used on such restorations being possible the necessity of some other materials to make is more aesthetic.

The reference device, CAD/CAMouflage Milling Block, has a same intended use that one of the G-CAM intended use but more restricted. The CAD/CAMouflage Milling Block physical presentation is different as is presented as a block with smaller width dimensions than the disc. Its usefulness is intended for small parts so that is only classified as EBF- Material, Tooth Shade, Resin and EBG – Crown and Bridge Temporary Resin.

The differences with G-CAM and those two predicate devices do not affect the safety and effectiveness of the device when used as labeled.

VI. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE PROPOSED DEVICE AND THE PREDICATE DEVICES *(21 CFR 807.92(a)(6))*

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Graphenano Dental has used the FDA's Guidance for Industry and FDA Staff – **"Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions"** for comparing its G-CAM with the Primary Device, JUVORA Dental Disc, and Reference device, CAD/CAMouflage Milling Block. Both are legally marketed devices under 21 CFR 807.92(a)(3) classified as Class II. The technological characteristics comparison table (Table 1) outline and provides the difference, similarities and the substantial equivalency of G-CAM and the cited predicate and reference devices.

SUMMARY OF SUBSTANTIAL EQUIVALENCE DISCUSSION:

Most of the G-CAM technological characteristics are substantially equivalent to the predicate device JUVORA Dental Disc. Both are thermoplastic materials, available in disc format and designed to be processed with a CAD/CAM system. The main difference is that they are composed of different raw materials. Both devices have been evaluated under the applicable standards for their intended use and they achieve the required values established by those.

When compared to the primary and reference predicate devices, the intended use and technological characteristics of G-CAM doesn't raise new issues related to safety and effectiveness. Based on the information provided in this submission, G-CAM is substantially equivalent to the primary predicate and reference devices.

The differences on physical properties and chemical compositions between G-CAM and the predicate devices do not impact safety and effectiveness. The finished presented product is biocompatible regardless of the material variation.

In general, we consider the proposed device to be substantially equivalent to the predicate device and consider that any differences between the proposed and predicate and reference devices will not pose new concern.

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Table.1 Comparison with predicate and reference Device

Feature	**Proposed Device:** G-CAM	**Primary Predicate:** JUVORA™ Dental Disc	**Reference Device:** CAD/CAMouflage Milling Block	**Similarities & Differences** (wh difference with the predicate an explanation will be given)
Manufacturer	Graphenano Dental, S.L.	Juvora, Ltd.	Prismatik Dentalcraft, Inc.	-
510(k) Nº	K220329	K160918	K160425	-
Class	Class II	Class II	Class II	**Same**
Device description	Thermoplastic dental disc	Thermoplastic dental disc	Composite Restorative Material	**Same** Primary Predicate Equivalent to Reference Device
Product code- Regulation description	EBF – Material, Tooth Shade Resin EBG – Crown and Bridge Temporary Resin EBI – Denture Relining, Repairing, Rebasing Resin	EBI – Denture Relining, Repairing, Rebasing Resin EBF – Material, Tooth Shade Resin EBG – Crown and Bridge Temporary Resin	EBF – Material, Tooth Shade Resin EBG – Crown and Bridge Temporary Resin	**Same** as Primary Predicate Equivalent to Reference Device EBI not included on the reference device codes as larger structures could be milled on a disc (i.e. dentures) than on the size block.
Classification	21 CFR 872.3690 21 CFR 872.3770 21 CFR 872.3760	21 CFR 872.3760 21 CFR 872.3690 21 CFR 872.3770	21 CFR 872.3690 21 CFR 872.3770	**Same** as Primary Predicate Equivalent to Reference Device
Indications for Use	G-CAM discs are intended to be used for the manufacture of full and partial removable dentures, implant overdentures as well as permanent and temporary restorations such as anterior or posterior crowns and bridges, inlays, onlays, veneers, copings and substructures.	The JUVORA™ Dental Disc is a thermoplastic dental disc. They are intended to be used for the manufacture of: i) Full and partial removable dentures and implant overdentures. ii) Copings, substructures (cemented or uncemented), frameworks for permanent and transitional anterior or posterior crowns and bridgework.	CAD/CAMouflage Milling Block is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. The CAD/CAMouflage Milling Block is made for fabricating temporary and permanent restorations such as inlays, onlays, veneers and full crown restorations.	**Substantially Equivalent** G-CAM therefore could be used a direct monolithic solution wh means that it does no need using ot materials to make aesth restorations while the prim predicate disc would normally n other material to show a m aesthetic solution.

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Technical characteristics	Flexural Modulus ISO20795 >2000MPa	3200 MPa +/-7% (ISO 20795)	3995 MPa (ISO 20795)	-	**Equivalent.** Despite being different materials, t properties are similar and the standard requirements are achiev
	Flexural strength ISO20795 >65MPa ISO10477 ≥ 50MPa	140 MPa +/-7% (ISO 20795) 148 MPa (ISO 10477)	165 MPa (ISO 20795) 192 MPa (ISO 10477)	> 100 MPa (ISO 10477)	
	Surface hardness	88 ShoreD (ISO 48-4)	-	-	
		19,5 KHN (ASTM E384)			
	Water absorption ISO20975 <32 µg/mm³ ISO10477 ≤40 µg/mm³	4 µg/mm³ (ISO 20795)	Water absorption 5 µg/mm3 (ISO 20795)	Water absorption < 40 µg/mm3 (ISO 10477)	
	Residual monomer ISO20795 <2,2%	<0.004% (ISO 20795)	-	-	
	Water solubility ISO20975 <1,6 µg/mm³ ISO10477 ≤7.5 µg/mm³	<0.5 µg/mm³ (ISO 20795)	-	< 7.5 µg/mm3 (ISO 10477)	
	Compressive strength (MPa)	156 MPa (ISO 5833)	-	-	

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	Filler particle size distribution (µ)	21,5 µ (ISO 13320)	-	-	
Performance testing		Conforms with ISO 20795-1 Conforms with ISO 10477	Conforms with ISO 20795-1 Conforms with ISO 10477	Conforms with ISO 4049 Conforms with ISO 10477	**Same**
Wearing time		Permanent and temporary	Permanent and temporary	Permanent and temporary	**Same**
Usage		Single patient	Single patient	Single patient	**Same**
Patient population		Suitable for everyone	Suitable for everyone	Suitable for everyone	**Same**
Prescription/OTC		Prescription Use Only	Prescription Use Only	Prescription Use Only	**Same**
Intended as an intraoral device		Yes	Yes	Yes	**Same**
Device components		No components	No components	No components	**Same**
Fixed/removable		Fixed / Removable	Fixed / Removable	Fixed / Removable	**Same**
Design		Disc	Disc	Block	**Same** as Primary Predicate Different to Reference Device
Appliance design		CAD/CAM milling	CAD/CAM milling	CAD/CAM milling	**Same**
Supplied Sterile / Nonsterile		Non- sterile	Non- sterile	Non- sterile	**Same**
Material		Polymethylmethacrylate PMMA (Polymethylmethacrylate) resin doped with graphene	PEEK-OPTIMA™ LT1	Ceramic-filled nanohybrid Polymer resin	**Difference/ Equivalence** Despite the differences in formulat between the subject device and predicate, they can be conside equivalent, as these differences d not affect clinical performance a safety. These Materials are commo used in the dental sector and all them achieve the applicable stand requirements.
Raw material:		Monomer Resin Graphene GNF-LS	PEEK (Polyetheretherketone)	Polymer resin with fillers and Pigments	**Difference/ Equivalence** Despite the differences in formulat between the subject device and

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				predicate, they can be conside equivalent since these differen does not affect clinical performa and safety. Materials commonly u in the dental sector and all of th pass the requirements of the standa
Manufacturing	Powder + Liquid methacrylate-based resins with graphene powder mixed and heat cured	PEEK can be processed by conventional methods used to process other plastics such as injection molding, extrusion, blow molding, and thermoforming	Powder + Liquid methacrylate-based resins with fillers and pigments mixed and heat cured	**Different** to the primary predicate due to the difference in material **Same** to Reference device
Maintenance	Oral hygiene	Oral hygiene	Oral hygiene	**Same**
Cleaning	Not specified	Not specified	Not specified	**Same**
Biocompatibility	Biocompatible	Biocompatible	Biocompatible	**Same**
Shelf life	5 years	10 years	Not specified	**Difference/ Equivalence** The G-CAM shelf life is evalua using the real-time testing method. the first produced discs have less t 10 years we can't ensure with t method that shelf life is arriving to t age, even if we believe so. Then provide, the confirmed by the r time testing, 5 years. The shorter va on shelf life is not substantial due the already explained reasons.

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IDENTIFICATION OF THE RISK ANALYSIS METHOD

G-CAM has conducted a preliminary hazard analysis which identify risks, including risk of mechanical failure, toxicity and adverse tissue reaction, improper use, and incompatibility with other dental devices. The Failure Modes Effect Analysis (FMEA) showed that all risks, when reduced as far as possible, were acceptable. There were no so severe risks found to cause severe damage or that lead to the death of a patient. The device mechanical properties are comparable to predicate devices. The biocompatibility testing showed that G-CAM is biocompatible. The labeling of the device is designed to reduce the risk of improper use.

DISCUSSION OF THE DEVICE CHARACTERISTICS

To reduce the risk of mechanical failure, G-CAM was designed according to applicable standard to its intended use. In addition, each production is subjected to an exhaustive quality control to check that the product is in accordance with its technical specifications. Also, to reduce the risk of mechanical failure cause of milling errors, specific information is given to the professional clients in documents like Instructions for Use, Work process, Design Parameters Sheet and Labelling. Moreover, G-CAM is a thermoplastic solid material, so additional curing steps are not needed which prevents improper fabrication due to varying curing or working times.

To reduce the risk of toxicity and adverse tissue reaction, G-CAM was tested against biocompatibility standards as specified by ISO 7405:2008, Dentistry - Evaluation of biocompatibility of medical devices used in dentistry. Moreover, G-CAM labeling is designed to reduce the risk of improper use.

DESCRIPTION OF THE PERFORMANCE ASPECTS *(21 CFR 807.92 (b)(1)(2))*

The testing of the performance aspects was performed to recognized standards, such as ISO 20795-1 and ISO 10477. (see Table 1 for specific application knowledge). There are no deviations to the procedure of the standard for the tests performed.

VII. NON-CLINICAL PERFORMANCE DATA

SECTION 05 – 510(k) SUMMARY

SUMMARY DISCUSSION OF NON-CLINICAL DATA:

The subject device has been subject to bench to determine conformance to performance specifications and requirements taking account of its intended use and following all recommendations set out in FDA Document "Dental Composite Resin Devices-Premarket Notification [510(k)] Submissions".

Non-clinical testing performed in foreseeable operating conditions showed correct operation of the device as per its intended use and specifically included mechanical performance.
Clinical testing is not required to demonstrate substantial equivalence as the indications for use are like legally marketed devices and the design is like designs previously cleared under a premarket notification.

RELIANCE OF STANDARDS

The G-CAM product has demonstrated conformance with the non-clinical performance requirements through evaluation and testing in accordance with the following standards:

• Chemical and physical testing having under considerations ISO 4049; ISO 20795-1 and IS0 10477 (Compression, Elastic modulus, Bending strength, Water absorption and Residual monomer, radiopaque...)

• Biocompatibility check for G-CAM material composition per ISO 7405 where the use of ISO 10993 is specified. Results for Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, Subchronic Toxicity by Subcutaneous Implantation, Material-Mediated Pyrogenicity, Genotoxicity and Carcinogenicity concluded that the device is biocompatible.

The results of this non-clinical testing show that the strength of the G-CAM product is sufficient for its intended use and is substantially equivalent to the legally marketed predicate device.

SUMMARY DISCUSSION OF CLINICAL DATA

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Non-clinical test data are submitted to support this premarket notification and to establish substantial equivalence. No clinical studies are submitted.

VIII. CONCLUSIONS

The results of the above-described studies demonstrate that the G-CAM discs are substantially equivalent in safety and effectiveness to the cleared primary predicate device and to the reference device based on the results of the physical property and biocompatibility testing.