



September 29, 2025

Graphenano Dental S.L.  
% Dave Yungvirt  
CEO  
Third Party Review Group, LLC  
7 Giralda Farms, Suite 120A  
Madison, New Jersey 07940

Re: K253236  
Trade/Device Name: G-Block  
Regulation Number: 21 CFR 872.3690  
Regulation Name: Tooth shade resin material  
Regulatory Class: Class II  
Product Code: EBF, EBG  
Dated: September 26, 2025  
Received: September 29, 2025

Dear Dave Yungvirt:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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](mailto: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  
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

## Indications for Use

510(k) Number (if known)

K253236

Device Name

G-BLOCK

Indications for Use (Describe)

G-BLOCK is intended to be used for the fabrication of permanent and temporary restorations such as dental implant prostheses, crowns, bridges, inlays, onlays and veneers.

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

**DATE PREPARED:** 28 September 2025  
**SUBMITTER NAME:** Graphenano Dental S.L.  
**SUBMITTER ADDRESS:** Polígono Industrial Táctica. Calle 2A, n.º 1.  
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**CONTACT PERSON:** Eva María Navarro Sáez, QA/RA Manager  
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**II. DEVICE** (21 CFR 807.92(a)(2))

**DEVICE TRADE NAME:** G-BLOCK  
**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

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

K220329 G-CAM

**Reference Predicate:**

K160425 CAD/CAMouflage Milling Block

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

G-BLOCK is a compact block made of graphene-doped polymer suitable for the manufacture of dental prostheses using CAD/CAM technology. The polymer is based on polymethyl methacrylate (PMMA) doped with graphene (an allotrope of carbon).

G-BLOCK is intended to be used for the fabrication of permanent and temporary restorations such as dental implant prostheses, crowns, bridges, inlays, onlays and veneers.

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

## **510(k) SUMMARY**

- ❖ G-BLOCK, compounded of polymethyl methacrylate (PMMA) doped with Graphene, is manufactured using the heat-curing method.
- ❖ G-BLOCK 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-BLOCK presents high deformation resistance and stress limit, thus avoiding the formation of cracks and fractures.
- ❖ G-BLOCK is low density making the prosthesis lightweight.
- ❖ G-BLOCK increases the material hardness comparing with acrylic resins used in dentistry.
- ❖ G-BLOCK has colour stability.
- ❖ G-BLOCK has wide chromatic range, even within the same piece, making it look extremely natural.
- ❖ G-BLOCK is chemically inert.
- ❖ G-BLOCK water absorption is 4 µg/mm<sup>3</sup> and a solubility of 0.5 µg/mm<sup>2</sup>. The release of residual monomer is minimum, with a percentage of 0.004% of residual monomer. Thanks to these physical properties G-BLOCK offers a durable and safety treatment.

G-BLOCK is available in different formats, sizes and colors, having all variations the same physicochemical characteristics.

### **DEVICE DESIGN DESCRIPTION**

The device is presented in the form of a polymer block glued to an aluminum pin that allows the device to be fixed on the milling machine so that the block can be milled to obtain dental prostheses with the use of specific CAD/CAM equipment.

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

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

- **Monochroma**, is made of a pure colour matching the dentin.

## **510(k) SUMMARY**

- **Multichroma**, has a chromatic spectrum based on the natural colour imitating the optical effects of the natural dentition.

Both variants are presented in two **sizes**: 14 and 40.

G-BLOCK device is available in the following **colours**, A1, A2, A3, A3.5, B1, B2, BL1, BL2, C2 (according to G-CAM shade guide).

G-BLOCK are provided non-sterile and as a single use device.

G-BLOCK must be used only by professionals as dental lab technicians and / or dentist.

G-BLOCK 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-BLOCK is made is stable and can be stored for an extended period of 5-year shelf life.

## **510(k) SUMMARY**

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

As established in the Indications for Use Statement:

"G-BLOCK is intended to be used for the fabrication of permanent and temporary restorations such as dental implant prostheses, crowns, bridges, inlays, onlays and veneers."

G-BLOCK is classified under two of the three product codes included in the primary predicate device, G-CAM. Those codes are the following: EBF – Material, Tooth Shade, Resin; EBG – Crown and Bridge Temporary Resin. The intended use of G-BLOCK is reduced compared to G-CAM due to the different shape and dimensions, but both are equivalent. Specifically, one indication of G-BLOCK is that it 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.

The reference device, CAD/CAMouflage Milling Block has the same physical presentation as G-BLOCK as is presented as well by a block shape. The block has smaller dimensions than the disc (primary predicate device shape). 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 as the device proposed.

The differences with G-BLOCK 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))

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-BLOCK with

## **510(k) SUMMARY**

the Primary Device, G-CAM, 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-BLOCK and the cited predicate and reference devices.

### **SUMMARY OF SUBSTANTIAL EQUIVALENCE DISCUSSION:**

The G--BLOCK technological characteristics are the same as the predicate device G-CAM. Both are thermoplastic materials, designed to be processed with a CAD/CAM system. The main difference is that they are available in different shapes and, therefore, the anchorage to the milling machine is different as well. The primary predicate has a disc shape, and the proposed G-BLOCK has a block shape but is composed of exactly the same 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-BLOCK doesn't raise new issues related to safety and effectiveness. Based on the information provided in this submission, G-BLOCK is substantially equivalent to the primary predicate and reference devices.

The differences in physical properties and chemical compositions between G-BLOCK and the predicate devices do not impact safety and effectiveness. The finished product presented is biocompatible regardless of the shape 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-BLOCK	Primary Predicate: G-CAM	Reference Device: CAD/CAMouflage Milling Block	<b>Similarities &amp; Differences</b> (when difference with the predicate an explanation will be given)
<b>Manufacturer</b>	Graphenano Dental, S.L.	Graphenano Dental, S.L.	Prismatik Dentalcraft, Inc.	<b>Same</b> as Primary Predicate
<b>510(k) N°</b>	-	K220329	K160425	-
<b>Class</b>	Class II	Class II	Class II	<b>Same</b>
<b>Device description</b>	Polymer dental block	Polymer dental disc	Composite Restorative Material	<b>Same</b> as Primary Predicate Equivalent to Reference Device
<b>Product code- Regulation description</b>	EBF – Material, Tooth Shade Resin EBG – Crown and Bridge Temporary Resin	EBF – Material, Tooth Shade Resin EBG – Crown and Bridge Temporary Resin EBI – Denture Relining, Repairing, Rebasing Resin	EBF – Material, Tooth Shade Resin EBG – Crown and Bridge Temporary Resin	<b>Same</b> as Reference Device Equivalent to Primary Predicate  EBI not included for G-BLOCK as larger structures could be milled on a disc (i.e. dentures) not on a block.
<b>Classification</b>	21 CFR 872.3690 21 CFR 872.3770	21 CFR 872.3690 21 CFR 872.3770 21 CFR 872.3760	21 CFR 872.3690 21 CFR 872.3770	<b>Same</b> as Reference Device Equivalent to Primary Predicate

### 510(k) SUMMARY

<b>Indications for Use</b>	G-BLOCK is intended to be used for the fabrication of permanent and temporary restorations such as dental implant prostheses, crowns, bridges, inlays, onlays and veneers	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.	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.	<b>Partially same</b>  G-Blocks have shorter indications for use than the primary predicate device which means that all the indications for use from the proposed device are indications for the primary predicate.	
<b>Technical characteristics</b>	Flexural Modulus ISO20795 >2000MPa	3200 MPa +/-7% (ISO 20795)	3200 MPa +/-7% (ISO 20795)	-	<b>Same</b> as Primary predicate and equivalent to reference device
	Flexural strength ISO20795 >65MPa ISO10477 ≥ 50MPa	140 MPa +/-7% (ISO 20795) 148 MPa (ISO 10477)	140 MPa +/-7% (ISO 20795) 148 MPa (ISO 10477)	> 100 MPa (ISO 10477)	
	Surface hardness	88 ShoreD (ISO 48-4)	88 ShoreD (ISO 48-4)	-	
		19,5 KHN (ASTM E384)	19,5 KHN (ASTM E384)		
	Water absorption ISO20975 <32 µg/mm <sup>3</sup> ISO10477 ≤40 µg/mm <sup>3</sup>	4 µg/mm <sup>3</sup> (ISO 20795)	4 µg/mm <sup>3</sup> (ISO 20795)	Water absorption < 40 µg/mm <sup>3</sup> (ISO 10477)	
	Residual monomer ISO20795 <2,2%	<0.004% (ISO 20795)	<0.004% (ISO 20795)	-	
Water solubility	<0.5 µg/mm <sup>3</sup>	<0.5 µg/mm <sup>3</sup>	< 7.5 µg/mm <sup>3</sup>		

## 510(k) SUMMARY

	ISO20975 <1,6 µg/mm <sup>3</sup> ISO10477 ≤7.5 µg/mm <sup>3</sup>	(ISO 20795)	(ISO 20795)	(ISO 10477)	
	Compressive strength (MPa)	156 MPa (ISO 5833)	156 MPa (ISO 5833)	-	
	Filler particle size distribution (µ)	21,5 µ (ISO 13320)	21,5 µ (ISO 13320)	-	
	Radio-opacity (mm Al)	Non-radiopaque	Non-radiopaque	-	
<b>Performance testing</b>		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	<b>Same</b>
<b>Wearing time</b>		Permanent and temporary	Permanent and temporary	Permanent and temporary	<b>Same</b>
<b>Usage</b>		Single patient	Single patient	Single patient	<b>Same</b>
<b>Patient population</b>		Suitable for everyone	Suitable for everyone	Suitable for everyone	<b>Same</b>
<b>Prescription/OTC</b>		Prescription Use Only	Prescription Use Only	Prescription Use Only	<b>Same</b>
<b>Intended as an intraoral device</b>		Yes	Yes	Yes	<b>Same</b>
<b>Device components</b>		No components	No components	No components	<b>Same</b>
<b>Fixed/removable</b>		Fixed / Removable	Fixed / Removable	Fixed / Removable	<b>Same</b>
<b>Design</b>		Block	Disc	Block	<b>Same</b> as Reference Device <b>Different</b> to Primary Predicate
<b>Size</b>		Size14: 12 x 14 x 18mm Size40: 15.5 x 19 x 39 mm	Diameter 98mm Diameter 95mm	Size14: 12 x 14 x 18mm	<b>Same</b> as Reference Device <b>Different</b> to Primary Predicate
<b>Appliance design</b>		CAD/CAM milling	CAD/CAM milling	CAD/CAM milling	<b>Same</b>
<b>Supplied Sterile / Nonsterile</b>		Non- sterile	Non- sterile	Non- sterile	<b>Same</b>
<b>Material</b>		Polymethylmethacrylate PMMA (Polymethylmethacrylate) resin doped with graphene	Polymethylmethacrylate PMMA (Polymethylmethacrylate) resin doped with graphene	Ceramic-filled nanohybrid Polymer resin	<b>Same</b> as Primary predicate and equivalent to reference device

### 510(k) SUMMARY

<b>Raw material:</b>	Monomer Resin Graphene GNF-LS	Monomer Resin Graphene GNF-LS	Polymer resin with fillers and Pigments	<b>Same</b> as Primary predicate and equivalent to reference device
<b>Manufacturing</b>	Powder + Liquid methacrylate-based resins with graphene powder mixed and heat cured	Powder + Liquid methacrylate-based resins with graphene powder mixed and heat cured	Powder + Liquid methacrylate-based resins with fillers and pigments mixed and heat cured	<b>Equivalent</b> to Reference device as new steps are added to mill the block shape and to add the anchorage pin to the block. <b>Same</b> to Primary predicate
<b>Maintenance</b>	Oral hygiene	Oral hygiene	Oral hygiene	<b>Same</b>
<b>Cleaning</b>	Not specified	Not specified	Not specified	<b>Same</b>
<b>Biocompatibility</b>	Biocompatible	Biocompatible	Biocompatible	<b>Same</b>
<b>Shelf life</b>	5 years	5 years	Not specified	<b>Same</b> The G-BLOCK shelf life is based on G-CAM shelf life calculation as each block is made by the same raw materials and method as G-CAM and, as well, the storage conditions are the same and the packaging equivalent, only changing in design.

## **510(k) SUMMARY**

### **IDENTIFICATION OF THE RISK ANALYSIS METHOD**

G-BLOCK 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-BLOCK 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-BLOCK was designed according to applicable standard to its intended use. In addition, each production is subjected to 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-BLOCK 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, the material that is milled was tested against biocompatibility standards as specified by ISO 7405:2008, Dentistry - Evaluation of biocompatibility of medical devices used in dentistry. Moreover, G-BLOCK 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.

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### VII. NON-CLINICAL PERFORMANCE DATA

#### **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-BLOCK 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 ISO 10477 (Compression, Elastic modulus, Bending strength, Water absorption and Residual monomer, radiopaque...)
- Biocompatibility check for 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-BLOCK product is sufficient for its intended use and is substantially equivalent to the legally marketed predicate device.

## **510(k) SUMMARY**

### **SUMMARY DISCUSSION OF CLINICAL DATA**

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-BLOCK is substantially equivalent in safety and effectiveness to the cleared primary predicate device and to the reference device based on the results of the physical properties and biocompatibility testing.