September 9, 2022

Creamed GmbH & Co. Produktions- und Handels KG
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K222723
Trade/Device Name: AMBARINO High-Class
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth shade resin material
Regulatory Class: Class II
Product Code: EBF
Dated: September 2, 2022
Received: September 8, 2022

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 (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)*

K222723

Device Name
AMBARINO® High-Class

Indications for Use *(Describe)*
AMBARINO® High-Class is indicated for fabrication of inlays / onlays, laminate veneers, anterior and posterior full crown restorations, and implant crowns and bridges by dental professionals and manufacturers using a dental CAD/CAM system.

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

510(k) Number: K222723

Submitter: Creamed GmbH & Co. Produktions- und Handels KG
Tom-Mutters-Str. 4a, 35041 Marburg, Germany

Contact: Robert Lemmer, President, Tel: +49 (0) 6421.168993.0, creamed.fda@gmail.com

Prepared By: Rich McComas, US Agent, +1 (480) 755.1155

Date Prepared: August 5, 2022

Device Identification

Trade Name:	AMBARINO® High-Class
Common Name:	Restorative resin material
Classification Name:	Tooth shade resin material
Regulation Number:	872.3690
Product Code:	EBF
Class:	Class II
Classification Panel:	Dental

Legally Marketed Predicate Device:

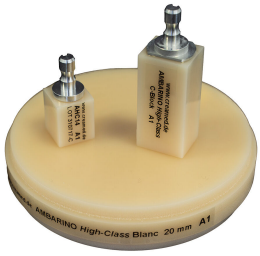
- Shofu Block HC (K130841); Manufacturer: SHOFU DENTAL

Device Description: The AMBARINO® High-Class CAD/CAM formed materials consist of interpenetrating networks of glass ceramic and polymer material to form a solid block of material. The unique marriage of the two materials creates a dual-network hybrid, which lends the positive physical properties of each individual material to the other. This results in a material with significantly lower brittleness compared to a pure ceramic and better abrasion behavior than a pure resin (similar to natural enamel). This non-sterile material is milled in a dental CAD/CAM machine into restorative form for single patient use.

Statement of Intended Use: AMBARINO® High-Class is indicated for fabrication of inlays / onlays, laminate veneers, anterior and posterior full crown restorations, and implant crowns and bridges by dental professionals and manufacturers using a dental CAD/CAM system.

Substantial Equivalence: Information provided in this application shows that the product is substantially equivalent to the predicate device. Comparisons of the physical properties of the AMBARINO® High-Class to the predicate devices are included in this application.

The table below compares AMBARINO® High-Class to the predicate device with respect to its physical state, structure, materials, mechanical properties, indications for use, biocompatibility and performance testing, and provides detailed information regarding the basis for the determination of substantial equivalence.

Elements of Comparison	Predicate Device	Subject Device	Similarities / Differences
Device Name	Shofu Block HC	AMBARINO® High-Class	-
Manufacturer	SHOFU DENTAL	Creamed	-
510(k) #	K130841	Pending	-
Product Code	EBF, EBG	EBF	-
Regulation	§872.3690	§872.3690	Same
Class	II	II	Same
Review Panel	Dental	Dental	Same
Device Image			-
Indications for Use	For fabrication of inlays / onlays, laminate veneers, anterior and posterior full crown restorations, and implant crowns and bridges by dental labs and manufacturers using a dental CAD/CAM system.	For fabrication of inlays / onlays, laminate veneers, anterior and posterior full crown restorations, and implant crowns and bridges by dental professionals and manufacturers using a dental CAD/CAM system.	Same
Physical State	Cured blocks and discs in a variety of shapes and shades	Cured blocks and discs in a variety of shapes and shades	Same
Structure	Polymer resin / ceramic hybrid composite	Polymer resin / ceramic hybrid composite	Same
Methacrylate	39% UDMA, TEGDMA	29% UDMA, BDDMA	Similar. The subject

-based Resin Matrix			and predicate devices contain UDMA in their resin matrix.
Filler Content	61% inorganic silica-based glass and silica	70% inorganic silica-based glass and barium glass	Similar
Sizes	14, 98	14, 40, 98, 100	The subject device size ranges fall within those of the predicate devices.
Flexural Strength	191 MPa	175 MPa	Similar
Modulus of Elasticity	9.6 GPa	9.9 GPa	Similar
Compressive Strength	472 MPa	490 MPa	Similar
Packaging	One disc per box, or for mandrel mounted blocks, five to a box	One disc per box, or for mandrel mounted blocks, six small or two large to a box	Same, based on physical state.
Usage	Single Patient, multiple use	Single Patient, multiple use	Same
Sterility	Non-Sterile	Non-Sterile	Same
Biocompatibility	Conforms with ISO 10993-1	Conforms with ISO 10993-1	Same
Performance	Conforms with ISO 4049	Conforms with ISO 4049	Same

Non-Clinical Performance Data: As part of demonstrating substantial equivalence of AMBARINO® High-Class to the predicate device, Creamed submitted final finished devices for extensive testing in accordance with the applicable parts of the following voluntary standards, as well as to the company's own internal test protocols:

- ISO 4049, Dentistry – Polymer-based RestorativeMaterials
- ISO 7405, Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
- ISO 10993-1, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process

Testing evaluated flexural strength, flexural modulus, compressive strength, and biocompatibility of the subject device, as well as other related physical properties. The subject device exceeded all minimum test standards, and all documented test results were substantially equivalent to the predicate device.

Design Characteristics: The geometry of the AMBARINO® High-Class material is shaped into solid block or disc forms as defined by the CAD/CAM manufacturer. The material will be inserted into the CAM machine and milled into its final form, then polished and ready for placement thereafter. This design is substantially equivalent to the predicate device.

Biocompatibility: The functionality of AMBARINO® High-Class as well as their conformance to design input was determined by non-clinical laboratory testing. AMBARINO® High-Class has been tested and meets the biocompatibility requirement.

Conclusion: AMBARINO® High-Class has the same or similar intended use, indications for use, physical attributes, and are fabricated into permanent tooth restorations using the same CAD/CAM manufacturing methods as Shofu Block HC. Additional sizes are available for the submitted device, but within the same range of sizes. The submitted device utilizes a slightly higher percentage of resin and therefore is a little less brittle and has a slightly lower flexural strength, but within the range of substantial equivalence. All performance data of the two devices are similar, and both exceed the minimum requirements. Any minor differences in the materials used to make the subject device when compared to the predicate device have been successfully evaluated by the manufacturer through extensive performance and biocompatibility testing on their device, such that the information submitted to the FDA demonstrates that the subject device is as safe and effective as the predicate device and does not raise any new questions of safety and effectiveness.

AMBARINO® High-Class, as designed and manufactured by Creamed, have been determined to be substantially equivalent to Shofu Block HC.