November 24, 2021

Perfect Fit Crowns, LLC
Tim Torbenson
Regulatory Consultant
evo820, LLC
1 Baya Street
Rancho Mission Viejo, California 92694

Re: K211345
Trade/Device Name: C-30 Crown Kit
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF, EMA
Dated: September 27, 2021
Received: September 27, 2021

Dear Tim Torbenson:

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

Section 4: Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/06/2020
See PRA Statement below.

510(k) Number *(if known)*

K211345

Device Name

C-Crown Kit

Indications for Use *(Describe)*

The C-30 Crowns are indicated for the use as a permanent Posterior Dental Crown

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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Section 5: 510(K) Summary for Perfect Fit Crowns LLC C-30 Crown Kit

1. Submitter

Owner's Name:	Perfect Fit Crowns LLC
Address:	1128 Royal Palm Beach Blvd, #166 Royal Palm Beach, FL 33411
Phone: Fax:	954-415-5639 N/A
Contact Person:	Steve Ziskind, CEO
Representative/Consultant:	Tim Torbenson evo820, LLC 1 Baya Street Rancho Mission Viejo, CA 92694 Telephone: +1 (916) 844-5267 E-mail: tim.torbenson@evo820.com
Date summary Prepared:	April 25, 2021

2. Device Name

Proprietary Name:	C-30 Crown Kit
Common/Usual Name:	tooth shade resin material, dental cement
Primary Classification Name:	tooth shade resin material
Primary Product Code:	EBF
Primary Regulation Number:	21 CFR 872.3690
Secondary Classification Name:	dental cement
Secondary Product Code:	EMA
Secondary Regulation Number:	21 CFR 872.3275
Device Class:	II

3. Predicate Device

Bego VarseoSmile Crown Plus K201668

4. Reference Device

Visalys CemCore, Visalys Cem Core Try In Paste (K191527)

5. Device Description:

The C-30 Crown Kit is a permanent tooth solution for single-unit restoration, adhesively cemented. The C-30 Crown Kit contains 3 components required for the chairside direct assembly of a posterior permanent crown.

1. The C-30 Sleeve, manufactured from VarseoSmile Crown Plus the 510(k) cleared (K201668) material has an external aspect that matches the internal aspect of the C-30 Crown, also manufactured with the same VarseoSmile Crown Plus (K201668) 510(k) cleared material. This material is a light cured, ceramic filled, methacrylate-based resin for the production of permanent single crowns. The sleeve is used as a containment vessel holding the 510(k) cleared Visalys CemCore, Visalys Cem Core Try In Paste (K191527) Adhesive Cement & CoreBuild-up which surrounds the prepared tooth created by the dentist. This match of the two units assures a perfect fit with a minimal gap of 5-15 microns between the C-30 Crown and the C-30 Sleeve.

2. The Visalys CemCore, Visalys Cem Core Try In Paste. (K191527) is used to treat the bonding surface of the sleeveand the Visalys CemCore, Visalys Cem Core Try In Paste. (K191527) is used to fill up the gap between the prepped tooth structure and the C-30 Sleeve. Once bonded and cured, the process continues.

3. The C-30 Crown now fits perfectly over the C-30 Sleeve and is bonded in place with the Visalys CemCore, Visalys Cem Core Try In Paste. (K191527) used consistent with its instructions for use.

6. (Revised) Summary of the Technological Similarities/Differences

Similarities:

The 2 components used to develop the direct C-30 sleeve/crown are manufactured by Perfect FitCrown, LLC with the VarseoSmile Crown Plus (K201668) material.

The C-30 Crowns are direct restorations used by dental professionals to construct custom dental posterior restorations chairside that are substantially equivalent to the laboratory manufactured crowns using the VarseoSmile Crown Plus (K201668) in general composition. These same manufacturing processes using Predicate material for the C-30 Sleeves and Crowns are as safe and effective as the Predicate.

Same Material Used for Finished Device – The Subject device is manufactured with the Predicate

The C-30 Crown Kit material is manufactured from VarseoSmile Crown Plus (K201668) methacrylate-based resins, dental glass-filler, photo initiators and pigments. The C-30 Sleeve & Crown are printed to their specific STL configurations to accommodate each of the 64 differentforms as per the material's application stated in the VarseoSmile Crown Plus(K201668) Indications for Use.

The Subject and the Predicate, VarseoSmile Crown Plus (K201668), finished devices are all the same cured-resin materials indicated for the fabrication of dental prosthetic devices.

The Subject and Predicate devices accomplish this by means of CAD/CAM technology. No differences in material properties or manufacturing process that do not alter or impact the ability of the Subject device to be used for its intended use.

In all cases, the Subject using the Predicate material in their devices have been demonstrated to be safe and effective for their intended use through non-clinical performance testing.

Material Shades Used in the C-30 Crown – A2 & A2.5 The Subject devices are manufactured using the Predicate A2 &A2.5 material. Manufacturing Subject devices are substantially equivalent to Predicate.

Differences:

The C-30 Crown components are fully cured predicate material and prefabricated to accommodate chairside crown sizing, try-in and delivery.

The VarseoSmile Crown Plus (K201668) material is delivered to the laboratory or dentist office in is resin form using CAD/CAD technology to be 3D printed to meet patient specifications.

The C-30 Crown components are only available in 2 shades. The VarseoSmile Crown Plus(K201668) is available in VITA Shades.

7. Non-clinical Testing:

The C-30 Sleeve and Crown are manufactured from VarseoSmile Crown Plus (K201668) methacrylate-based resins, dental glass-filler, photo initiators and pigments. This material is manufactured and cured following the VarseoSmile Crown Plus (K201668) Instructions for Use as demonstrated in Section 9: Device Description and Function.

The submitted non-clinical testing for the VarseoSmile Crown Plus (K201668) applies to the same material characteristics and validates intended use of the Subject.

The Visalys CemCore, Visalys Cem Core Try In Paste (K191527) included with the C-30 Crown Kit is in the original manufacturer's packaging and all non-clinical data submitted in the K191527 documents provided validating the material's intended use.

Conclusion

Overall, the non-clinical Subject device data has the following similarities to the legally marketed Predicate device:

- Material of the devices are the same
- Have nearly identical Indications for Use and Intended Use
- Have very same Technological Characteristics.
- There are no differences in Technological Characteristics with the Predicate device
- Find the IFU for the Reference devices is substantially equivalent to the Technological Characteristics of the Subject.
- Any differences have been mitigated by demonstration of the Subject device to be suitable

forintended use through Predicate additional non-clinical performance testing. Sections

- Sterilization and Shelf Life, Biocompatibility & Material Testing all demonstrate and validate substantial equivalence to Predicate of the Subject.