Figaro Crowns, Inc.
Kyle Rose
Quality Manager
1628 Quail Ridge Circle
Woodbury, Minnesota 55125

July 3, 2018

Re: K172952
Trade/Device Name: Figaro Crowns Anterior Crown Kit, Figaro Crowns Posterior Crown Kit
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: March 30, 2018
Received: April 3, 2018

Dear Kyle Rose:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

For
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172952

Device Name
Figaro Crowns Anterior Crown Kit
Figaro Crowns Posterior Crown Kit

Indications for Use *(Describe)*
The Figaro Preformed Dental Crown is intended for restoration of permanent teeth with a single unit 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.

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

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5. 510(k) Summary K172952

Date of Preparation: **30-Mar-2018**

Attn:

Figaro Crowns, Inc.

1628 Quail Ridge Circle

Woodbury, MN USA 55125

%Kyle Rose

Tel: 404.717.9358

Email: rookqualitysytems@gmail.com

Official Contact: Kyle Rose Quality Manager

Trade Name:

Figaro Crowns Anterior Crown Kit

Figaro Crowns Posterior Crown Kit

Common Name: Dental material, filling/restorative, polymer based

Classification Name: Tooth Shade Resin Material

Classification Regulations: 21 CFR 872.3690

Product Code EBF

Classification: Class II

Predicate Device: K143694 Rhondium One-Visit-Crown (OVC)

Device Description:

The Figaro Crown is a permanent preformed resin crown used on adult patients. The crown is designed for permanent (>30 days) tooth restoration to restore, size, strength, chewing ability and /or to improve appearance. The preformed crowns are manufactured to specific sizes for improved fit. The crowns go through a finishing

process and are not intended to the manipulated by the dentist. Sizing is exclusively determined by the dentist for each crown and patient. The crown is secured to the patient's mouth with standard adhesion techniques. Once the crown is cemented in place it should fully encase the portion of the tooth that lies above the gum line. The Figaro Preformed crown is made of layers fiberglass held together by epoxy resin. Small amounts of Titanium Dioxide and Yellow Iron oxide are added for cosmetic affect.

The crowns are designed for the following designs, Canine, Upper Premolar, Upper Molar, Lower Premolar, Lower Molar. The crowns are provided in one size.

Indications for Use:

The Figaro Crowns are intended for restoration of permanent adult teeth with a single unit crown.

Environment of Use:

The Figaro Crowns are available for prescription only and intended to be used by a licensed dental professional such as DDS or DMD. Not for use by the general public or OTC.

Contradictions: None

Substantial Equivalence Discussion of Comparison to Predicates:

The Figaro Crowns are viewed as substantially equivalent to the predicate device based on the equivalencies listed below.

Indications-

The indication for use is identical to the predicate K143694 Rhondium One-Visit-Crown (OVC).

Technology-

The technology used to create the preformed resin crown is similar to the predicate. The Figaro Crown does not require any additional uncured custom layers and therefore poses less risk that the predicate.

Materials-

The materials are similar cured resins that have been found to meet ISO 10993 requirements and thus can be substantially equivalent to the safety of the predicate.

Comparison	Figaro Crowns Preformed Dental Crown	Rhondium One-Visit-Crown (OVC)
Crown Description	Preformed single tooth crown for one visit restoration	Preformed single tooth crown for one visit restoration
Teeth to be restored	Adult Canine, Upper Premolar, Upper Molar, Lower Premolar, Lower Molar.	Upper and lower canines, premolars, and molars
Specific crown design	N=5 designs: Canine, Upper Premolar, Upper Molar, Lower Premolar, Lower Molar.	N=8 designs : Upper Premolar, Upper Molar, Lower Premolar, Lower Molar Each in Left and Right designs
Crown Sizes	Each design provided in 1 size	Each design provided in 6 sizes: XS, S, M, L, XL, XXL
Crown material	Heat cured polymer composite resin reinforced with fiberglass	Light-cured polymer composite resin

Non-clinical Performance Testing:

We have performed a number of bench tests to demonstrate the Figaro Crowns perform with in the specifications. These tests included:

- Flexural Strength
- Flexural Modulus
- Tensile Strength
- Tensile Modulus
- Charpy Index

Substantial Equivalence Conclusion

The Figaro Crowns and the predicate device have similar indications for use and intended use and provide a similar range of designs and sizes for restoration. Both devices are provided nonsterile for single use only.