OperArtLLC
% Kevin Walls
Principal Consultant
Regulatory Insight, Inc.
33 Golden Eagle Lane
Littleton, Colorado 80127

December 13, 2017

Re: K171167
Trade/Device Name: Prodigio Stain Powder
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain powder for clinical use
Regulatory Class: Class II
Product Code: EIH
Dated: November 18, 2017
Received: November 20, 2017

Dear Kevin Walls:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171167

Device Name
Prodigio Stain Powder

Indications for Use *(Describe)*
The Prodigio Stain Powder includes the following 6 sets of stains and dental porcelains:

Prodigio Stain Kit is a porcelain stain system designed for easy application and natural fluorescent properties. This dental porcelain stain system can be used with most commercially available porcelain restorations, where porcelain's ability to mimic natural tooth appearance is important. The system provides optimum esthetics with the most consistently reliable results for the full range of shades.

The Prodigio Stain Kit is ideal for high and low production laboratories and is available in 16 classic Vita® shades as well as Neutral Brown, Complex Gray, Blue Gray, Ochre; Rust and Red for matching bleached dentition with CTE Ranges of 13.7 to 15.1. The full assortment is 22 Stains, 1 powdered glaze and 1 liquid glaze.

The stains in the Prodigio Stain Kit fire at 900 degrees C

Prodigio Stain Kit is identical to the SN2000Y kit in function and content except that the stains in the SN2000Y kit fire at 750 degrees C

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.