DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 4, 2017

Blue Sky Bio
% Angela Blackwell
Senior Consultant
Blackwell Device Consulting
888 E. Belvedere Rd., Suite 212
Grayslake, Illinois 60030

Re: K163251
Trade/Device Name: Life Essence Universal Porcelain System
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: June 27, 2017
Received: July 5, 2017

Dear Angela Blackwell:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Andrew I. Steen -S

for Lori Wiggins, MPT, CLT
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)* K163251

Device Name
Life Essence Universal Porcelain System

Indications for Use *(Describe)*
The Life Essence Universal Porcelain System is a dental porcelain material to be used in conjunction with metal, zirconia, or pressable ceramic framework in the construction of crowns and/or bridgework 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

Life Essence Universal Porcelain System

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Date Prepared: August 4, 2017

General Information	
Trade Name	Life Essence Universal Porcelain System
Common Name	Porcelain powder for dental use
Predicate 510(k)	Luminesse Porcelain K140848
Product Code	EIH
Regulation No.	872.6660 Porcelain Powder for Clinical Use
Classification	Class II

Device Description:

Life Essence Universal Porcelain is dental porcelain used by dental technicians to create crowns, bridges, and veneers. It consists of three categories: low fusing, high fusing, and zirconia porcelain. The application, indication, and performance is the same for all three categories; therefore, it is a porcelain system. It includes Pressable Ingots, Opaque Pastes, Opaque Powders, Opacious Dentins, Dentins, Incisal Powders, Stains, Incisal Transluscents, Dentin Modifiers, Correction Powder, Glaze Powder, Glaze Liquid, Spray Glaze, Modeling Liquid, and Opaque Liquid. The dental technician will use various components of the system to create the specific, desired dental prosthetic, for the sole use of individual dental patients. It is for prescription use only.

Indications for Use:

The Life Essence Universal Porcelain System is a dental porcelain material to be used in conjunction with metal, zirconia, or pressable ceramic framework in the construction of crowns and/or bridgework and veneers.

Primary Predicate Indications for Use:

The Luminesse Porcelain System is a dental porcelain material to be used in conjunction with metal, zirconia, or pressable ceramic framework in the construction of crowns and/or bridgework and veneers.

Technological Characteristics:

Life Essence Universal Porcelain is used to veneer or press over the appropriate base materials (metal or zirconia). In order to prevent cracking and avoid damage of the restoration due to the thermally-induced stress, the average coefficient of thermal expansion has been adjusted to a coefficient of thermal expansion of the appropriate base materials, which allows fusion to the base materials. This is the main technological characteristic of the dental porcelains in general, and it is shared by the subject device and predicate device. Bench testing (according to ISO 6872:2008 Dentistry-Ceramic Materials) to determine flexural strength, solubility and glass transition temperature was provided. See tables below for the specific product types and what class they are according to the standard.

Class	**Dental Powder**	**Life Essence Low-Fusing Porcelain Powder**
1	Core ceramic powder	Opaque Powder, Dentin Modifier
2	Dentin	Dentin Powder, Opacious Dentin
3	Enamel	Incisal
4	Neck material	Margin
5	Transparent Material	Incisal Translucent
6	Stains	Universal Stain Shades
7	Add-on material	Correction Powder
8	Glaze materials	Universal Glaze
Type 2, class 1	Core ceramic powder	Pressable Pellets

Class	**Dental Powder**	**Life Essence High-Fusing Porcelain Powder**
1	Core ceramic powder	Opaque Powder
1.1	Core ceramic paste	Opaque Paste
2	Dentin	Dentin Powder
2.1	Dentin Modifier	Opacious Dentin, Dentin Modifier, Gingival
3	Enamel	Incisal
4	Neck Material	Margin, Neck Translucent
5	Transparent material	Incisal Translucent
6	Stains	Universal Stain Shades

7	Add-on material	Correction Powder
8	Glaze materials	Universal Glaze

Class	**Dental Powder**	**Life Essence Zirconia Porcelain Powder**
1	Core ceramic powder	Dentin Modifier
2	Dentin	Dentin Powder, Gingival
3	Enamel	Incisal
4	Neck material	Margin, Neck Translucent
5	Transparent Material	Opal Translucent, Incisal Translucent
6	Stains	Universal Stain Shades
7	Add-on material	Correction Powder
8	Glaze materials	Universal Glaze

Conclusion:

All components found in Life Essence Universal Porcelain are identical to components in the predicate device system. It has the same technological characteristics, chemical composition, manufacturing process, and same indications for use as the predicate devices. Components of this product have not changed in any way from the predicate that would adversely affect biocompatibility; therefore, it is determined that no biocompatibility testing is necessary for this product.

Life Essence Universal Porcelain, as designed and manufactured, is substantially equivalent to the predicate device in terms of indications for use, chemical composition, manufacturing and technological characteristics.