DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Aesthetic-Press, LLC
% Pamela Papineau
President
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
Ayer, Massachusetts 01432

June 5, 2017

Re: K163228
Trade/Device Name: ApVolution System
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: April 25, 2017
Received: May 2, 2017

Dear Pamela Papineau:

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,

Mary S. Runner -A

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)*
K163228

Device Name
APVolution System

Indications for Use *(Describe)*
The APVolution System is used to fabricate prostheses for missing/damaged teeth. The APVolution pressable ingots are pressed onto metal alloy (APVolution M) or zirconia (APVolution Z) frames by dental technicians to fabricate ceramic restorations. APVolution M and APVolution Z ceramic layering powders and/or pastes are used to layer or build up the pressed ceramic to final tooth morphology. APVolution S ceramic ingots are used to create all-ceramic restorations. AP Stains and Glaze are used during the fabrication process to achieve the correct shade.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Appendix A – 510(k) Summary (revised) K163228

Date: April 25, 2017

Owner's Name: Aesthetic-Press, LLC
Address: 6613 State Road 54
New Port Richey, FL 34653
Telephone: 415-692-5372
Fax: 415-723-7075

Contact Person: Pamela Papineau, RAC (US, EU, CAN)
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
Ayer, MA 01432
Telephone: (978) 772-3552
Fax: (978) 796-5460

Subject Device:
Trade Name: APVolution System
Common Name: Dental Ceramic
Product Code: EIH
FDA Regulation: 21 CFR 872.6660 – Porcelain Powder for Clinical Use
Device Classification: Class II

Predicate Device:
Product Name: DCceram System
Common Name: Dental Ceramic
Product Code: EIH
FDA Regulation: 21 CFR 872.6660 – Porcelain Powder for Clinical Use
Device Classification: Class II
Premarket Notification: K141400

Indications for Use
The APVolution System is used to fabricate prostheses for missing/damaged teeth. The APVolution pressable ceramic ingots are pressed onto metal alloy (APVolution M) or zirconia (APVolution Z) frames by dental technicians to fabricate ceramic restorations. APVolution M and APVolution Z ceramic layering powders and/or pastes are used to layer or build up the pressed ceramic to final tooth morphology. APVolution S ceramic ingots are used to create all-ceramic restorations. AP Stains and Glaze are used during the fabrication process to achieve the correct shade.

Device Description:
The APVolution System consists of several silica glass ceramic materials used to create all-ceramic, ceramic-metal or ceramic-zirconia dental restorations. The APVolution System includes

three ceramic ingots for use in the fabrication of all-ceramic (APVolution S), press-to-metal (APVolution M) or press-to-zirconia (APVolution Z) restorations. The system also includes powders and pastes for use in build-up and shaping of the final restoration, as well as shades and glazes for use in achieving acceptable aesthetics. The APVolution System components are listed below in the Substantial Equivalence summary table.

Substantial Equivalence

The Aesthetic-Press APVolution System is substantially equivalent to the Ceramay DCceram System (K141400). Substantial equivalence, which is summarized below, is based on indications for use and device physical and technological characteristics.

	Aesthetic-Press APVolution System (current submission)	**Ceramay DCceram System (K141400)**
Device Common/Usual Name	Dental Ceramic	Dental Ceramic
Device Class	Class II	Class II
Product Code / Regulation	EIH / 21 CFR 872.6660	EIH / 21 CFR 872.6660
Regulation Name	Porcelain Powder for Clinical Use	Porcelain Powder for Clinical Use
Prescription Use	Rx Only	Rx Only
Indications for Use Statement	The APVolution System is used to fabricate prostheses for missing/damaged teeth. The APVolution pressable ceramic ingots are pressed onto metal alloy (APVolution M) or zirconia (APVolution Z) frames by dental technicians to fabricate ceramic restorations. APVolution M and APVolution Z ceramic layering powders and/or pastes are used to layer or build up the pressed ceramic to final tooth morphology. APVolution S ceramic ingots are used to fabricate all-ceramic restorations. AP stains and glaze are used with the APVolution ceramic ingots, powders and/or pastes during the fabrication process to achieve the correct shade.	The DCceram System is used to fabricate prostheses for missing/damaged teeth. The DCceram pressable ceramic ingots are pressed onto metal alloy (APVolution M) or zirconia (APVolution Z) frames by dental technicians to fabricate ceramic restorations. DCceram 12.5 and DCceram 9.2 ceramic layering porcelains and shades are used to layer or build up the pressed ceramic to final tooth morphology and shade on the particular framework (DCceram 9.2 zirconia substructures; DCceram 12.5 metal substructures). The DCceram conceptPress ceramic ingots are used to fabricate all-ceramic restorations. DCceram conceptArt stains and shades may be used with DCceram conceptPress or DCceram 9.2 ceramics.
System Components	APVolution M ceramic ingots APVolution Z ceramic ingots APVolution S ceramic ingots APVolution M porcelain powders APVolution Z porcelain powders APVolution M opaque ceramic paste AP stains & glazes	DCceram 9.2 ceramic ingots DCceram 12.5 ceramic ingots conceptPress ceramic ingots DCceram 9.2 liner/layering porcelain DCceram 12.5 liner/layering porcelain DCceram 12.5 opaque ceramic paste conceptArt stains, shades & glazes
Range of Vita® Tooth Shades	A1 – D4	A1 – D4

	Aesthetic-Press APVolution System (current submission)	**Ceramay DCceram System (K141400)**
ISO 6872 Type I/II, Class 1a Materials	APVolution M & APVolution ceramic ingots APVolution M & APVolution Z porcelain powders APVolution M opaque ceramic paste AP stains & glazes	DCceram 9.2 & DCceram 12.5 ceramic ingots DCceram 9.2 & DCceram 12.5 porcelain powders DCceram 12.5 opaque ceramic paste conceptArt stains, shades & glazes
ISO 6872 Type II, Class 4b Materials	APVolution S ceramic ingots	conceptPress ceramic ingots
ISO 7405 Biocompatibility	ISO 10993-5 cytotoxicity test: L929 cell monolayer proliferation/inhibition during contact with extended (7 day) extraction using DMSO in complete cell culture medium	Meets requirements of ISO 7405 Dentistry – Evaluation of Biocompatibility of Medical Devices Used in Dentistry
ISO 6872 Performance Testing	• Identification of Types & Classes of System Components • Uniformity • Freedom from Extraneous Materials • Mixing & Condensation Properties (Class I Ceramics) • Physical & Chemical Properties • Flexural Strength • Linear Thermal Expansion Coefficient • Glass Transition Temperature • Chemical Solubility • Radioactivity	Meets performance testing requirements of ISO 6872 Dentistry – Dental Ceramics
Sterile Device	No	No
Prescription Only	Yes	Yes
Single Use	Yes	Yes

Performance Testing:

The APVolution System components have been tested to confirm compliance with ISO 6872 *Dentistry – Ceramic Materials*. This Abbreviated 510(k) submission includes a Declaration of Conformity to the performance testing methods and acceptance criteria defined in ISO 6872. The specific inspections and tests included in this declaration are listed in the table above. This submission also includes biocompatibility test reports to demonstrate that the APVolution System components meet the biocompatibility requirements described in ISO 7405:2008 *Dentistry – Evaluation of biocompatibility of medical devices used in dentistry.* Biocompatibility testing consisted of ISO 10993-5 cytotoxicity testing where the proliferation or inhibition of an L929 cell monolayer was evaluated following direct contact with an extended-time (7 day) extract of the system components using DMSO in complete culture medium. The APVolution components met all requirements of the ISO 6872 and ISO 7405 standards.

Conclusion:

The Aesthetic-Press APVolution System has been demonstrated to be substantially equivalent to the predicate device as demonstrated through comparison of the system indications for use,

description of system components, biocompatibility testing in accordance with ISO 7405, performance testing in accordance with ISO 6872, and device labeling.