

K123613

## 510(K) SUMMARY

Synspar Advanced Pressable Ceramic

Rev. 1

FEB 20 2013

Contact: Donna Marie Hartnett  
Company: Ardent, Inc. 175 Pineview Drive, Amherst, NY 14228  
(716) 691-0010

Date Prepared: December 3, 2012

Trade Name: Synspar Advance Pressable Ceramic (Pellets)

Classification Name: Porcelain Powder for Clinical Use (872.6660)

Predicate Devices: PrismaTik NetPress (K050144)  
IPS InLine PoM System (K071848)

Device Description: Synspar Advance Pressable Ceramic (Pellets) is a dental porcelain system composed of a leucite-ceramic which utilizes a press-on or conventional heat-pressing technique for dental restoration fabrication.

### Intended Use:

#### Press-on-Metal Restorations

- Single unit fully anatomical crowns in the anterior and posterior regions
- Fully anatomical splinted crowns and bridges in the anterior and posterior regions
- Compatible with dental alloys in the CTE range  $13.6-14.6 \times 10^{-6}/K$  (25–500°C). Alloys should be copper-free and contain less than 14% silver.

#### Pressed All-ceramic Restorations

- Adhesively cemented single unit anterior all-ceramic restorations (crowns, inlays, onlays, veneers)

#### The material is contraindicated for:

- Pressing over metal frameworks beyond the CTE range
- Very deep sub-gingival preparations
- Patients with substantially reduced residual dentition
- Patients with bruxism and
- Use on alloys with a silver (Ag) content of more than 14% and any alloys comprising copper (Cu) beyond trace quantities

#### Other limitations of use:

- Combination with any other ceramic materials unless specified by Instructions for Use
- Pressing Synspar Advance Pressable Ceramic (Pellets) thinner than 0.8mm
- Layering of Synspar Advance Incisal and Body materials
- Pressing over metal frameworks that do not exhibit the required minimum thickness for copings or connectors.

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**Technological Characteristics:** The Synspar Advance Pressable Ceramic (Pellets) represents a shade modification (pigment percentages) to the Prismatic NetPress (510k No. K050144) and can be used in the same "Press on Metal" technique as IPS InLine POM (K071848). Both Synspar Advance and Prismatic Netpress pellets represent modifications to the Synspar and Avante Porcelain Systems by Ardent Inc. Changes have been made in the device's formulation and processing technique.

**Testing Summary:** Synspar Advance Pressable Ceramic (Pellets) was tested according to ISO 6872:2008 and is classified as Type II Class 1a&b and 2a esthetic dental ceramic. Synspar Advanced Pressable Ceramic was also tested for Metal-Ceramic Bond Strength in accordance with ISO 9693:1999, A1:2005 Dentistry: Metal-ceramic dental restorative systems for its use in the Press on Metal technique. The device has been tested for flexural strength, chemical solubility, CTE, Metal-Ceramic Bond Strength, and Glass transition temperature and the results of such testing are substantially equivalent to the predicate devices.

All of the components have been used in legally marketed devices. The formulations have not been changed in ways that may adversely impact safety or efficacy.

We believe that the prior use of the components in legally marketed devices, the similarity in the formulations between the modified device and the marketed device, and the data provided regarding the modifications to the marketed device support the safety and effectiveness of the Synspar Advance Pressable Ceramic (Pellets) for the intended use.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-002

February 20, 2013

Ardent, Inc.  
C/O Donna Marie Hartnett, Esq.  
Director QA/Regulatory Affairs  
Ivoclar Vivadent, Inc.  
175 Pineview Drive  
Amherst, NY 14228

Re: K123613

Trade/Device Name: Synspar Advance Pressable Ceramic Pellets  
Regulation Number: 21 CFR 872.6660  
Regulation Name: Porcelain Powder for Clinical Use  
Regulatory Class: II  
Product Codes: EIH  
Dated: November 20, 2012  
Received: November 23, 2012

Dear Ms. Hartnett:

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

**Kwame O. Ulmer**

Anthony D. Watson, B.S., M.S., M.B.A.  
Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and  
Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K123613

Device Name: Synspar Advance Pressable Ceramic Pellets

### Indications For Use:

Synspar Advance Pressable Ceramic (Pellets) is a leucite ceramic system for:

#### Press-on-Metal Restorations

- Single unit fully anatomical crowns in the anterior and posterior regions
- Fully anatomical splinted crowns and bridges in the anterior and posterior regions
- Compatible with dental alloys in the CTE range  $13.6-14.6 \times 10^{-6}/K$  (25–500°C). Alloys should be copper-free and contain less than 14% silver.

#### Pressed All-ceramic Restorations

- Adhesively cemented single unit anterior all-ceramic restorations (crowns, inlays, onlays, veneers)

Prescription Use  AND/OR  
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner

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Susan Runner, DDS, MA

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(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

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