K071848

Ivoclar Vivadent, Inc.
175 Pineview Drive
Amherst, New York 14228

Tel: 800-533-6825
Tel: 716-691-0010
Extension: 2260
Fax: 716-691- 2294
Donna.Hartnett@ivoclarvivadent.us.com

ivoclar vivadent®
passion vision innovation

# 510(K) SUMMARY

AUG 3 0 2007

Contact: Donna Marie Hartnett

Date Prepared: July 3, 2007

Trade Name: IPS InLine PoM System

Classification Name: Porcelain Powder for Clinical Use (872.6660)

Predicate Devices: PTM System by Dentsply (K041335)

Device Description: IPS InLine PoM is a dental porcelain system composed of a leucite-ceramic which utilizes a press-on technique for dental restoration fabrication. The restoration is processed according to the lost wax technique. The opaqued metal framework is first waxed up in the desired shape and function and invested. After investment and burning out of the wax, the ductile ceramic – IPS InLine PoM ingot, is pressed into the previously created hollow space by means of a press furnace. After divesting the pressed objects, they are individually characterized using the new Shade/Stain and Glaze materials intended to be marketed with this System.

The InLine PoM System consists of a porcelain Opaquer, Porcelain Ingots, Touch up and Add-On Porcelain powders, and Shade, Stain and Glaze porcelain pastes with accompanying liquids.

Intended Use:

IPS InLine PoM is a leucite ceramic system for pressing fully anatomical restorations on metal crown and bridge frameworks after the application of opaquer, mainly in the posterior region. Alloy CTE range: 13.8 – 14.5 $10^{-6}K^{-1}$ 25-500 °C

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 with alloys with a silver content of more than 10%

Other limitations of use:

- Combination with any other ceramic materials
- Pressing IPS InLine PoM ingots thinner than 0.8mm
- Pressing of IPS InLine PoM ingots without a metal framework
- Layering of IPS InLine Dentin, Incisal, Deep Dentin, Margin, Impulse and Gingiva materials
- Pressing over metal frameworks that do not exhibit the required minimum thickness for copings or connectors.

Technological Characteristics: The IPS InLine PoM System represents a modification to the IPS Classic and IPS InLine porcelain systems by Ivoclar Vivadent. Changes have been made in the device's formulation and processing technique.

IPS InLine PoM was designed and tested in accordance with ISO 6872 for Dental Ceramic and ISO 9693 for Metal-ceramic dental restorative systems.

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 IPS InLine PoM System for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2007

Ms. Donna Marie Hartnett
Director of Quality Assurance/Regulatory Affairs and
Assistant Corporate Counsel
Ivoclar Vivadent, Incorporated
175 Pineview Drive
Amherst, New York 14228

Re: K071848
Trade/Device Name: IPS InLine PoM System
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: June 28, 2007
Received: July 12, 2007

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.

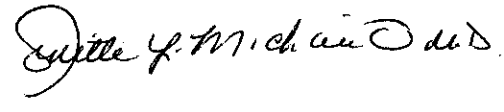
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

**510(k) Number (if known):** K071848

**Device Name:** IPS InLine PoM System
**Indications For Use:**

IPS InLine PoM is a leucite ceramic system for pressing fully anatomical restorations on metal crown and bridge frameworks after the application of opaquer, mainly in the posterior region. Alloy CTE range: 13.8 – 14.5 $10^{-6}K^{-1}$ 25-500 °C

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 with alloys with a silver content of more than 10%

Other limitations of use:

- Combination with any other ceramic materials
- Pressing IPS InLine PoM ingots thinner than 0.8mm
- Pressing of IPS InLine PoM ingots without a metal framework
- Layering of IPS InLine Dentin, Incisal, Deep Dentin, Margin, Impulse and Gingiva materials
- Pressing over metal frameworks that do not exhibit the required minimum thickness for copings or connectors.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)



Sun Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K071848