

510(k) SUMMARY

DENTSPLY

NAME & ADDRESS:

DENTSPLY International
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Fax (717) 854-2343
P. J. Lehn Telefax (717) 849-4343

SEP 11 1997

K971869

CONTACT: P. Jeffery Lehn

DATE PREPARED: May 19, 1997

TRADE OR PROPRIETARY NAME: FINESSE™ ALL-CERAMIC SYSTEM

CLASSIFICATION NAME: Porcelain Powder for Clinical Use 872.6660

PREDICATE DEVICE: DICOR® Castable Ceramic K830955A

DEVICE DESCRIPTION: The FINESSE™ ALL-CERAMIC SYSTEM is a glass-ceramic material designed to be used with Finesse™ Low-Fusing Porcelain. By combining the core material with the Finesse™ Low-Fusing Porcelain, the laboratory can offer the recognized aesthetics wear characteristic and chair-side polishability of Finesse™ Low-Fusing Porcelains combined with the aesthetic benefits of an all-ceramic system.

A dental restoration is prepared by placing a glass material in a heat and pressure deformable crucible. Heat is applied to the crucible to bring the glass to a "working" temperature. The glass is brought into contact with a mold having a preformed dental restorative cavity. The crucible is crushed and the molten glass is then injected into the mold. After cooling, the glass coping is removed from the mold. The glass restoration is heat treated to crystallize into a glass-ceramic. Finesse™ Low-Fusing Porcelain is then applied on the glass-ceramic coping to complete the restoration.

INTENDED USE: The FINESSE™ ALL-CERAMIC SYSTEM is used only with Finesse™ Low-Fusing Porcelain for the fabrication of dental restorations: for inlays, onlays, veneers, complete crowns on anterior teeth, and for single crowns on selected posterior teeth.

TECHNOLOGICAL CHARACTERISTICS: All components in the FINESSE™ ALL-CERAMIC SYSTEM have been used in predicate medical devices or have been found safe for dental use.

The FINESSE™ ALL-CERAMIC SYSTEM has been evaluated by the MEM Elution Test and found to be non-cytotoxic, by the Ames Mutagenicity Assay and found to be non-mutagenic, and by the Hamster Cheek Pouch Irritation Study (mucous membrane) and found to be a non-irritant.

We believe that the prior use of the components in predicate devices, the results of the toxicity and irritation testing, and the performance data support the safety and effectiveness of the FINESSE™ ALL-CERAMIC SYSTEM for the intended uses.

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JUL 21 1997



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 11 1997

Mr. P. Jeffrey Lehn
Director, Corporate Compliance & Regulatory Affairs
DENTSPLY International
570 West College Avenue
York, Pennsylvania 17405

Re: K971869
Trade Name: Finesse™ All-Ceramic System
Regulatory Class: II
Product Code: EIH
Dated: July 24, 1997
Received: July 25, 1997

Dear Mr. Lehn:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

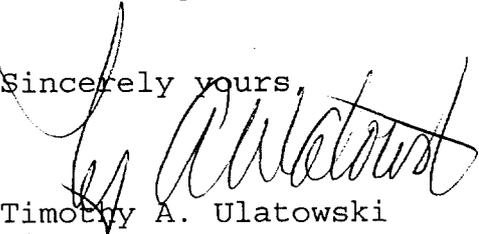
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 801.109)

510(K) Number: K971869

Device Name: FINESSE™ ALL-CERAMIC SYSTEM

Indications for Use:

Used only with FINESSE™ Low-Fusing Porcelain for the fabrication of dental restorations:
for inlays, onlays, veneers, complete crowns on anterior teeth, and for single crowns on
selected posterior teeth.

Susan Runnes
(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Dental, Infection Control,
and General Hospital Devices
510(K) Number: K971869
Prescription Use Yes OR Over-The-Counter Use No

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