K040635

510(k) SUMMARY

MAR 3 0 2004

DENTSPLY International
World Headquarters
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405-0872
P. J. Lehn Telefax (717) 849-4343

CONTACT: P. Jeffery Lehn

DATE PREPARED: March 8, 2004

TRADE OR PROPRIETARY NAME: CARRARA INTERACTION CERAMIC SYSTEM

CLASSIFICATION NAME: Porcelain powder for clinical use (872.6660)

PREDICATE DEVICES: Carrara Porcelain and Carrara Vincent Porcelain K981000

DEVICE DESCRIPTION: The CARRARA INTERACTION CERAMIC SYSTEM is a dental porcelain system used for the preparation of fixed prosthodontic devices.

The CARRARA INTERACTION CERAMIC SYSTEM consists of Paste Opaque, Dentine, Enamel, Margin, and Glaze porcelains.

INTENDED USE: The CARRARA INTERACTION CERAMIC SYSTEM is indicated for veneering of metal-ceramic or full ceramic restorative systems.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in the CARRARA INTERACTION CERAMIC SYSTEM have been used in legally marketed devices.

The CARRARA INTERACTION CERAMIC SYSTEM is very similar in formulation to legally marketed dental ceramics and has been on the European market since 2002 with over 1 million units placed. The CARRARA INTERACTION CERAMIC SYSTEM is produced from the same frits as Elephant's Carrara (K981000) and Antagon (K982129) Ceramics. Elephant veneering ceramics have been on the market since 1984. Therefore, it was determined that no biocompatibility testing was necessary.

We believe that the prior use of the components of the CARRARA INTERACTION CERAMIC SYSTEM in legally marketed devices, the performance data provided, and the historical use of the device in Europe support the safety and effectiveness of the CARRARA INTERACTION CERAMIC SYSTEM for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 0 2004

Mr. P. Jeffery Lehn
Director, Corporate Compliance and Regulatory Affairs
DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street
York, Pennsylvania 17405-0872

Re: K040635
Trade/Device Name: Carrara Interaction® Ceramic System
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: March 08, 2004
Received: March 10, 2004

Dear Mr. Lehn:

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 (301) 594-4613. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Chiu S. Lin, PhD
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 STATEMENT

(As Required by 21 CFR 807.87(e)

510(K) Number (if known): K040635

Device Name: **CARRARA INTERACTION CERAMIC SYSTEM**

Indications for Use:

The CARRARA INTERACTION CERAMIC SYSTEM is indicated for veneering of metal-ceramic or full ceramic restorative systems.

Prescription Use __X__ 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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K040635