

SEP 22 1999

K992161

### 510(k) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of SMDA and 21CFR § 807.92

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Submitted by: Nordiska Dental AB  
Box 1082  
S-262 21 Ängelholm  
Sweden

Product Manager: Charlotte Asserup

Fax Number: (+46) 461 44 33 99

Date Prepared: June 1, 1999

Device Name:

Proprietary Name: **CERANA**  
Common Name: Ceramic dental filling  
Classification: Class II, EIH

Identification of Predicate Devices

- **Ivoclar North America, Inc.** IPS Empress, Ivoclar North America, Inc., 175 Pineview Dr., Amherst, NY 14228; 510(k) number K913372.
- **Ivoclar North America, Inc.** SONICSYS Inlay, Ivoclar North America, Inc., 175 Pineview Dr., Amherst, NY 14228; 510(k) number K972648.
- **Lee Pharmaceuticals.** Precise ® Beta Quartz Glass-Ceramic Insert, Lee Pharmaceuticals, 1444 Santa Anita Avenue, P.O. Box 3836, South El Monte, CA 91733; 510 (k) number K912256

Device Description:

**CERANA** is an all-ceramic inlay that has the same translucency as enamel, can be finished and polished just like enamel and has the same natural color as enamel. The inlays are pre-etched, silanised and ready to use, when removed from the hygienic blister package.

Indication for Use:

**CERANA** is designed to be used in class I primary and secondary caries/replacement of filling; class II primary and secondary caries and replacement of filling; restoration of ceramic crowns and repair of ceramic inlays; and class IV restorations.

Technological Characteristics

CERANA, a prefabricated leucite-reinforced glass ceramic inlay, has been tested to show comparison with the IPS Empress predicate device material. In design and installation techniques it is similar to the Sonicsys inlay and Beta Quartz glass-ceramic insert predicate devices. In summary, no new technology, materials, or change in efficacy have been introduced in the manufacture of CERANA.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 22 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Nordiska Dental AB  
C/O Ms. Christine Emanuel  
Regulatory Affairs Consultant, TECSA  
TECSA Technical Services  
1205 De La Vina  
Santa Barbara, California 93101

Re: K992161  
Trade Name: CERANA  
Regulatory Class: II  
Product Code: EIH  
Dated: June 21, 1999  
Received: June 25, 1999

Dear Ms. Emanuel:

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 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). 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 (Pre-market 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 requirements, 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 pre-market notification submission does not affect any obligation you might have under sections 531

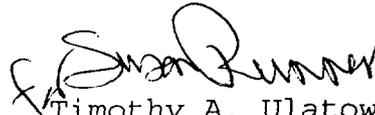
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4692. 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 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/dsma/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

Include the following "Indications For Use" page that contains the applicant's name, name of the device and the intended use of the device. The information, data and labeling claims in the entire the 510(k) submission must support and agree with the "indications for use" statement.  
\*For a new submission, do NOT fill in the 510(k) number blank.

### INDICATIONS FOR USE

Applicant: Nordiska Dental AB

510(k) Number (if known): N/A\*

Device Name: CERANA

Indications For Use:

CERANA is designed to be used in class I primary and secondary caries/replacement of filling; class II primary and secondary caries and replacement of filling; restoration of ceramic crowns and repair of ceramic inlays; and class IV restorations.

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

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Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use                        
Per 21 CFR 801.109

OR

Over-the-Counter                     

Susan Purn  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number 1992161