



2/12/99

Norian Corporation
Skeletal Repair Systems

10260 Bubb Road
Cupertino, CA 95014-4166

Phone 408 252 6800
Fax 408 252 3355

K983104

510(k) Summary

General Information

Classification Name: Bone Cement

Common Name: Endosseous Implant for Bone Filling and/or Augmentation

Device Trade Name: Norian® PDC™

Submitter's Name & Address: Norian Corporation
10260 Bubb Road
Cupertino, CA 95014-4166
(408) 252-6800

Contact Person: Kim Tompkins, Vice President, Regulatory Affairs, Quality Assurance, and Clinical Affairs

Summary Preparation Date: September 1998

Device Description

Norian PDC is a paste-like bone cement which is intended to fill and/or augment periodontal bone wall defects, extraction socket defects, and cysts or other defects in the alveolar ridge or wall. Norian PDC is an injectable and moldable, biocompatible, bone cement. The Norian PDC Reactants Pack contains the two sterile components used in Norian PDC: Calcium Phosphate Powder and Sodium Phosphate Solution. The Reactants Pack is mixed in a pneumatic mixer to form a smooth, viscous paste which is applied to the operative site. Norian PDC cures into a carbonated apatite that is substantially similar to the mineral component of bone, and over time, the Norian PDC is gradually resorbed over time.

Predicate Device

Norian PDC is substantially equivalent to legally marketed devices in the U.S. which are classified as endosseous implant for bone filling and/or augmentation, such as ∞-BSM™ Bone Substitute Material Kit (K962548) and Norian® Craniofacial Repair System™ (K973789). Any minor differences between Norian PDC and the predicate devices do not raise new questions of safety or effectiveness.

Intended Use

Norian PDC is intended to fill and/or augment periodontal bone wall defects, extraction socket defects, and cysts or other defects in the alveolar ridge or wall.

Device Testing

Testing was designed and performed to characterize Norian PDC Cement. Biocompatibility testing showed that Norian PDC Cement is acceptable for its intended use as a bone implant material. Norian Cement passed all tests, and showed no toxic, mutagenic or irritating effect.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 1999

Ms. Kim Tompkins
Vice President, Regulatory Affairs, Quality Assurance
and Clinical Affairs
Norian Corporation
10260 Bubb Road
Cupertino, California 95014-4166

Re: K983104
Trade Name: Norian® Periodontal/Dental Cement (PDC)™
Regulatory Class: III
Product Code: LYC
Dated: December 1, 1998
Received: December 3, 1998

Dear Ms. Tompkins

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 (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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 through 542 of

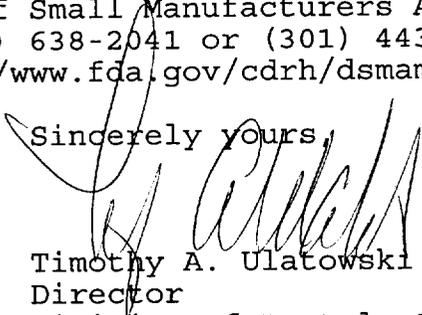
Page 2 - Ms. Tompkins

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" (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

510(k) Number (if known): **K983104**

Device Name: Norian® Periodontal/Dental Cement™ (PDC™)

Indications for Use:

Norian PDC Cement is intended to be used in the treatment of periodontal bone wall defects, extraction socket defects, and for repair of cysts or other defects in the alveolar ridge or wall.

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

_____ Concurrence of CDRH, Office of Device Evaluation (ODE) _____

Prescription Use
 (Per 21 CFR 801.109)

OR

Over-the-Counter Use _____

(Optional Format 1-2-96)

Susan Rimmer
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K983104