

MAY 15 1998

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510(k) Summary

K973789

General Information

Classification Name: Bone Cement
Common Name: Hydroxyapatite Cement (HAC)
Device Trade Name: Norian CRS™
Classification Code:

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

Establishment Registration:

Contact Person: Susan G. Marques, Manager, Regulatory Affairs
Summary Preparation Date: May 14, 1998

Predicate Device

Norian CRS™ is substantially equivalent to Osteogenics BoneSource® Hydroxyapatite Cement (K953339, K964537, K970400).

Device Description

Norian Craniofacial Repair System (Norian CRS) is a paste-like bone cement which is intended for the restoration or augmentation of bony contours in the craniofacial skeleton, such as burr hole voids and other cranial defects. Norian CRS is an injectable and moldable, biocompatible, bone cement. The Norian CRS Reactants Pack contains the two sterile components used in Norian CRS: Calcium Phosphate Powder and Sodium Phosphate Solution.

When the Reactants Pack is mixed, a smooth, viscous paste is formed. The paste is applied directly to the operative site, where it hardens in about 10 minutes to provide initial structural support. Within 24 hours, Norian CRS cures into a carbonated apatite that is similar to the mineral component of bone. The compressive strength of Norian CRS is approximately 50MPa. Over time, Norian CRS is gradually resorbed.

The Norian Mixer, Delivery Device, and Delivery Needles are used to mix and deliver the Norian CRS to the operative site.

Indications for Use

Norian CRS is intended for filling craniofacial defects in the restoration or augmentation of bony contours of the craniofacial skeleton (including fronto-orbital, malar, and mental areas) such as burr hole voids and other craniofacial defects, with a surface area no larger than 25cm².

510(k) Summary

Technological Characteristics

Norian CRS is comprised of monocalcium phosphate, monohydrate [MCPM, $\text{Ca}(\text{H}_2\text{PO}_4)_2 \cdot \text{H}_2\text{O}$], α -tricalcium phosphate [TCP, $\text{Ca}_3(\text{PO}_4)_2$], and calcium carbonate (CC, CaCO_3) to which a sodium phosphate solution is added to form a paste. The paste cures *in situ* at 37°C for approximately 12 hours. Within 24 hours, Norian CRS cures into a carbonated apatite that is similar to the mineral component of bone.

Performance Data

The following summaries present the results of Norian CRS *in vitro* testing:

X-ray Diffraction

The x-ray diffraction data demonstrates that set (initial hardening) occurs at about 10 minutes, and the reaction is greater than 90% complete by 24 hours. In addition, the x-ray diffraction patterns demonstrate that Norian CRS cures to become an apatite of low crystalline order with no by-products present.

pH Value Determination

Laboratory testing showed that the pH range of Norian SRS is 6.0–8.0. The testing measured the pH values both during and after setting.

Dimensional Verification

Norian SRS hardens in approximately 10 minutes at body temperature (37°C) with no significant dimensional changes (<1%) as determined by comparing the dimensions of molds with the dimensions of Norian CRS samples prepared from the same molds.

Solubility Testing

The solubility and solubility products of Norian CRS were found to be equivalent to the predicate device.

Porosity Testing

The average percent porosity of Norian CRS was found to be equivalent to the predicate device. Both materials resulted in microporous structures of polycrystalline apatite.

Biocompatibility Testing

Biocompatibility testing was conducted and performed in compliance with the Good Laboratory Practice regulation to evaluate Norian SRS. Norian SRS passed all tests, and showed no toxic, mutagenic or irritating effect. The test data showed that Norian SRS is acceptable for its intended use as a bone implant material.

Sterilization

The Norian CRS Reactants Pack is provided sterile and is for single use only. Sterilization is conducted using gamma radiation, following ANSI/AAMI ST32-1992, Method 3A/3B.

Substantial Equivalence

Norian CRS™ is substantially equivalent to Osteogenics BoneSource® Hydroxyapatite Cement (K953339, K964537, K970400). Like the predicate device, Norian CRS is a bone cement which hardens *in situ* to augment or restore bony contours in the craniofacial skeleton. Any minor differences between Norian CRS and the predicate device do not raise new questions of safety or effectiveness.

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 1998

Ms. Susan Marques
Manager, Regulatory Affairs
Norian Corporation
10260 Bubb Road
Cupertino, California 95014-4166

Re: K973789
Norian® CRS™ Craniofacial Repair System
Regulatory Class: II
Product Code: GXP
Dated: February 13, 1998
Received: February 17, 1998

Dear Ms. Marques:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device identified in your submission 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.

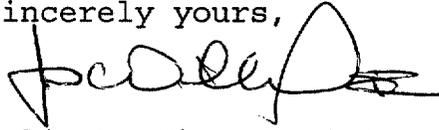
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Ms. Susan Marques

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) 594-4659. 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 at (301) 443-6597.

Sincerely yours,



fr Celia M. Witten, Ph.D., M.D.
Division Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): **K973789**

Device Name: Norian Craniofacial Repair System (CRS®) Bone Cement

Indications for Use:

Norian CRS is intended for filling craniofacial defects in the restoration or augmentation of bony contours of the craniofacial skeleton (including fronto-orbital, malar, and mental areas) such as burr hole voids and other craniofacial defects, with a surface area no larger than 25cm².

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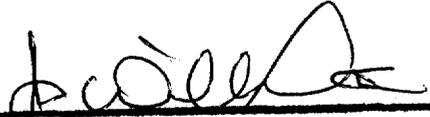
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____

(Optional Format 1-2-96)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973789