

SECTION 1

K102208

MAY - 6 2011

510 (K) SUMMARY

Submitted by:

Company Name: Orthogen LLC
Address: 505 Morris Avenue, Ste 104
Springfield, NJ 07081
Telephone: 973-467-2404
Fax: 973-467-1218

CONTACT PERSON:

Harold Alexander, Ph.D.
505 Morris Avenue, Suite 104
Springfield, NJ, 07081
Ph: 973-467-2404
Fax: 973-467-1218
Email : halexander@orthogencorp.com

DATE PREPARED: 08/03/2010

TRADE NAME: NanoGen (Nanocrystalline calcium sulfate particles)

COMMON NAME: Bone filling augmentation material

SUBSTANTIALLY EQUIVALENT TO:

SurgiPlaster K 011403, BoneGen-TR K 060285

DESCRIPTION of the DEVICE: NanoGen is a mixture of particles composed of densely packed grains of nanocrystalline calcium sulfate and medical grade calcium sulfate hemihydrate powder. The particles range from 400 – 850 microns in size. The particles of nanocrystalline calcium sulfate are purely synthetic and are manufactured from medical grade calcium sulfate hemihydrate through a proprietary process. Because of its unique structure, NanoGen undergoes controlled, slower degradation as compared to traditional calcium sulfate.

NanoGen is designed to set-up in vivo and may be used either alone or mixed with DFDBA (demineralized freeze-dried bone allograft) or autogenous bone in bone regenerative procedures. It is mixed with small amounts of normal saline to produce a putty-like paste and is then applied to the bone defects. Set NanoGen dissolves with time. The calcium present in NanoGen is believed to contribute to the mineralization of newly regenerated bone. In vitro dissolution studies conducted by incubating NanoGen particles in simulated body fluid confirmed that NanoGen undergoes degradation in 12 weeks as opposed to the 4 – 6 week degradation time found for medical grade calcium sulfate powder. This finding has been confirmed by in vivo studies.

510(k) Summary-Continued

INDICATIONS FOR USE:

NanoGen is indicated for use in the following ways; by itself in bone regenerative techniques; mixed with other suitable bone filling agents to prevent particle migration in an osseous defect; and, to provide a resorbable barrier over other bone graft materials.

COMPARISON WITH PREDICATE DEVICES:

1. Comparison of NanoGen and SurgiPlaster:

NanoGen is substantially equivalent to:

SurgiPlaster Calcium Sulfate hemihydrate Bone Graft Plaster K011403

Equivalency is determined by:

- ✓ NanoGen has the same indication for use and labeling claims.
- ✓ NanoGen has similar material composition.

Device Description	Device (NanoGen)	Predicate (SurgiPlaster)
Intended Use	<ol style="list-style-type: none">1. By itself in bone regeneration2. Mixed with other bone grafts3. Providing a resorbable barrier over other bone grafts	<ol style="list-style-type: none">1. By itself in bone regeneration2. Mixed with other bone grafts3. Providing a resorbable barrier over other bone grafts
Device Design	0.65 grams medical grade calcium sulfate particles 400 - 850 microns in size mixed with 0.35 grams medical grade calcium sulfate powder; regular set solution (saline) provided	Medical grade calcium sulfate hemihydrate powder, supplied with regular set (saline) and fast set (potassium sulfate) liquids
Composition of Materials	Medical grade calcium sulfate, normal saline (Regular Set)	Medical grade calcium sulfate, normal saline (Regular Set) and 4% Potassium sulfate solution (Fast Set)
Physical Properties	Completely resorbs in 10-12 weeks, mix of powder and particles	Resorbs in 4-6 weeks, provided in powder form

510(k) Summary-Continued

FDA-Recognized Standards	ASTM F2224-03 for properties of calcium sulfate 510(k) Sterility Review Guidance K90-1 ISO 11137-1:2006	ASTM F04.13.15 for properties of calcium sulfate EN 552, 554 and 556 for sterilization standard
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2. Comparison of NanoGen and BoneGen – TR:

NanoGen is substantially equivalent to:

BoneGen-TR K060285

Equivalency is determined by:

- ✓ NanoGen has the same indication for use and labeling claims.
- ✓ NanoGen is manufactured using same technology.
- ✓ NanoGen is sterilized in the same manner.

Device Description	Device (NanoGen)	Device (BoneGen – TR)
Intended Use	<ol style="list-style-type: none"> 1. By itself in bone regeneration 2. Mixed with other bone grafts 3. Providing a resorbable barrier over other bone grafts 	<ol style="list-style-type: none"> 1. Oral Surgery: Post-extraction 2. Periodontics: Intra-osseous defects. 3. Endodontics: Apicoectomy, Root perforations, Open apices. 4. Implantology: Dehiscences, fenestrations, sinus lifts.
Device Design	0.65 grams of medical grade calcium sulfate particles 400-850 microns in size mixed with 0.35 grams of medical grade calcium sulfate powder; regular set solution (saline) also provided.	Composite particles (425-850 micron) of medical grade calcium sulfate and PLLA (ratio of 96:4) supplied in 1.5 gram packs
Composition of Materials	Medical grade calcium sulfate, normal saline (Regular Set)	Medical grade calcium sulfate and PLLA

510(k) Summary-Continued

Physical Properties	Completely resorbs in 10-12 weeks, mix of powder and particles	Completely resorbs in 16 weeks, particle size range is 425 to 850 micron
FDA-Recognized Standards	ASTM F2224-03 for properties of calcium sulfate 510(k) Sterility Review Guidance K90-1 ISO 11137-1:2006	ASTM F2224-03 for properties of calcium sulfate ANSI/AAMI/ISO standard 11737-1995 for sterilization

SUMMARY of TESTING:

Orthogen LLC has 1) tested the chemical composition of Calcium Sulfate Hemihydrate used to make NanoGen by an independent laboratory to a recognized test method (USP NSF 18) and reported the results in this submission; and, 2) has provided extensive literature articles documenting the use of calcium sulfate particles as a bone augmentation material. Therefore this material has been qualified as biocompatible and safe for its intended use. This device is not marketed as non-pyrogenic.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

MAY - 6 2011

Harlod Alexander, Ph.D.
Chief Executive Officer
Orthogen, LLC
505 Morris Avenue, Suite 104
Springfield, New Jersey 07081-1033

Re: K102208
Trade/Device Name: NanoGen (nanocrystalline Calcium Sulfate Particles)
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: April 26, 2011
Received: April 27, 2011

Dear Dr. Alexander:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 102208

Indications for Use

510(k) Number K102208

Device Name: NanoGen (nanocrystalline calcium sulfate particles)

- Indications For Use:
1. By itself in bone regenerative techniques;
 2. Mixed with other suitable bone filling agents to prevent particle migration in an osseous defect; and,
 3. To provide a resorbable barrier over other bone graft materials.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan R. [Signature]
(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

Page 1 of 1

510(k) Number: K102208