

# SECTION 1

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510 (k) Summary

K060285

Rev. 16

Submitted by:

**Company Name:** BioLok International Inc.  
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Deerfield Beach, FL 33442  
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**Contact Person:** Harold Alexander, Ph.D.  
BioLok International Inc.  
Orthogen Biomaterials Division  
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**Date Prepared:** January 30, 2006

**Trade Name:** BoneGen-TR

**Common Name:** Bone filling augmentation material

**SUBSTANTIAL EQUIVALENCE:** BoneGen-TR is substantially equivalent in design, function and intended use to Orthogen Corporation's SurgiPlaster cleared as K011403 on September 11, 2001 (tradename changed to BioLok International Inc.'s BoneGen on June 21, 2005). The only difference is the addition of 4% PLLA to slow the degradation rate of the calcium sulfate hemihydrate. A second predicate device having substantially equivalent design, function and intended use is Lifecore Biomedical Inc.'s CalMatrix Calcium Sulfate Bone Graft Binder cleared as K041324 on June 19, 2004. This device, like BoneGen-TR, is a composite of calcium sulfate hemihydrate and an absorbable polymer. A third predicate device is OsteoBiologics, Inc.'s Polygraft Bone Graft Substitute cleared as K030288 on June 17, 2003. This device is substantially equivalent in function. The intended use of filling bony voids or gaps is equivalent except for the orthopaedic rather than dental emphasis. In design this material contains the two components of BoneGen-TR, calcium sulfate hemihydrate and polylactic acid containing polymer, in addition to polyglycolide fibers and a surfactant. A fourth predicate device is Atrix Laboratories, Inc.'s Atrisorb Bioabsorbable GTR Barrier cleared as K982865 on September 8, 1998. This device utilizes the PLA absorbable polymer as a bone contacting and repair material. It differs in that it does not contain calcium sulfate hemihydrate and softens the absorbable polymer with N-methyl-2-pyrrolidone.

**DESCRIPTION OF THE DEVICE:** BoneGen – TR is manufactured by BioLok-International Inc. It is a composite of medical grade calcium sulfate hemihydrate and poly (l lactic acid) in a 96:4 ratio. It is produced in pellet form: the size of pellets ranging from 425 – 850 microns. This composite undergoes slower degradation than calcium sulfate, overcoming the occasional disadvantage of rapid degradation of the pure medical grade calcium sulfate hemihydrate. It has a half-life of approximately 60 days and is usually completely degraded by 120 days. It can be used as a bone graft material on its own or it

can be combined with a pure medical grade calcium sulfate hemihydrate bone graft material such as BoneGen. BoneGen – TR will be presented in 1.5 gram packages. Bony defects can be packed with BoneGen – TR pellets and can be closed with calcium sulfate based, absorbable polymer based, collagen based or ePTFE based barriers. With time, BoneGen – TR pellets undergo degradation and is replaced by a calcium phosphate “trellis” that stimulate bone growth in the defect.

#### **INDICATIONS FOR USE:**

BoneGen-TR is indicated for use as follows:

1. By itself in bone regeneration procedures
2. Mixed with other bone graft materials (e.g. PRP, bone allograft, bone xenograft, demineralized freeze dried bone and/or a pure calcium sulfate based bone graft material)

#### **SUMMARY OF TESTING:**

BioLok International, Inc. has:

1) tested the chemical composition of BoneGen-TR by an independent FDA registered laboratory utilizing test method USP NSF 18. The poly(l lactic acid) is obtained from a supplier who has an FDA Device Master File for this material and has certified biocompatibility to ISO 10993-1 requirements for implantable contact greater than 30 days. Residual methylene chloride was determined by gas chromatography flame ionization (GC/FI). The chemical composition of the calcium sulfate hemihydrate has been tested by an independent laboratory (NAMSA) using the USP/NF monograph testing procedure. The material satisfied chemical purity as specified by ASTM Standard F2224-03, Standard Specification for High Purity Calcium Sulfate Hemihydrate or Dihydrate for Surgical Implants.

2) provided extensive literature documenting the use of calcium sulfate, poly (l lactic acid) and their composites in bone grafting procedures.

3) provided in vitro degradation profile testing and the results of an animal experiment conducted to study the function of BoneGen-TR as a bone graft material as compared to the first predicate device, BoneGen pure calcium sulfate hemihydrate.

Based upon this testing and literature data, BoneGen-TR has been demonstrated as biocompatible and safe for its intended use.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 16 2006

Bio-Lok International, Incorporated  
C/O Mr. Harold Alexander  
Orthogen Biomaterials Division  
505 Morris Avenue, Suite 104  
Springfield, New Jersey 07081

Re: K060285  
Trade/Device Name: BoneGen TR  
Regulation Number: 21 CFR 872.3930  
Regulation Name: Bone Grafting Material  
Regulatory Class: II  
Product Code: LYC  
Dated: January 30, 2006  
Received: February 6, 2006

Dear Mr. Alexander:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and have determined the device is substantially equivalent 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 (Premarket 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket 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.

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.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. An 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, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA.

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 (240) 276-0115. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 at (301) 443-6597.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu S. Lin', with a large, stylized flourish at the end.

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

K060285

**Indications for Use**

510(k) Number (if known):

Device Name: BoneGen TR

- Indications For Use:
1. Oral Surgery: Post-extraction.
  2. Periodontics: Infra-osseous defects.
  3. Endodontics: Apioectomy, Root perforations, Open apices.
  4. Implantology: Dehiscences, fenestrations, sinus lifts.

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Prescription Use  AND/OR Over-The-Counter Use   
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(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)

*Susan Purse*

Director, Technology, General Hospital  
Federal Dental Devices

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