JUL 17 2003

# 510(k) SUMMARY

| *Submitter* | *Contact* |
|---|---|
| OBI OsteoBiologics, Inc. | Gabriele G. Niederauer, Ph.D. |
| | Director of Research and Development |
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**Date of Summary**: January 24, 2003
**Revised**: July 9, 2003
**Common Name**: Resorbable Bone Void Filler
**Proprietary Name**: PolyGraft™ BGS; Bone Graft Substitute
**Device Classification**: Resorbable calcium salt bone void filler (Product Code 87MQV) is a Class II device, per 21 CFR 888.3045
**510(k) Number**: K030288

**Description of Device:** PolyGraft™ BGS is manufactured using a blend of poly(D,L-lactide-co-glycolide), calcium sulfate, polyglycolide fibers and surfactant. The PolyGraft™ BGS will be provided in a variety of shapes and sizes ranging from small, porous granules to preformed cylindrical plugs.

**Intended Use**: The PolyGraft™ BGS is to be used to fill bony voids or gaps caused by trauma or surgery that are not intrinsic to the stability of the bony structure. The PolyGraft™ BGS is intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

**Substantial Equivalence**: The PolyGraft™ BGS is substantially equivalent in design, function and intended use to the Wright Plaster of Paris Pellets cleared as K963562 on May 7, 1997 and ProOsteon™ 500R cleared as K980817 on Sept. 25, 1998.

**Testing**: Biocompatibility assessment performed by independent certified laboratories demonstrated the biocompatibility of the materials used for this device. Degradation testing performed in a simulated body fluid at 37 °C showed that the degradation rate is substantially equivalent to the predicate devices. OsteoBiologics performed a rabbit metaphyseal defect study to compare the bone formation of the PolyGraft™ BGS to the predicate devices. At six weeks, the PolyGraft™ BGS histologically showed bone formation similar to the predicate devices. Similarly, biomechanical properties of the bone defects treated with these graft materials were equivalent. The results from this side-by-side in vivo comparison demonstrated that PolyGraft™ BGS are substantially equivalent to the predicate devices, therefore supporting the suitability of the PolyGraft™ BGS for use in a clinical situation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2003

Gabriele G. Niederauer, Ph.D.
Director of Research and Development
Osteobiologics
12500 Network, Suite 112
San Antonio, TX 78249-3308

Re: K030288
Trade Name: PolyGraft BGS
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: June 25, 2003
Received: June 26, 2003

Dear Dr. Niederauer:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

*Indications for use (form)*

**INDICATIONS FOR USE**

**510(k) Number (if known):** K030288

**Device Name:** Polygraft BGS

**Indications For Use:**

The Polygraft BGS is to be used to fill bony voids or gaps caused by trauma or surgery that are not intrinsic to the stability of the bony structure. The Polygraft BGS is intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

(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)**

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030288

**Prescription Use** ✓ **OR** **Over-The-Counter Use** _____

**(Per 21 CFR 801.109)**