K043172

JAN - 7 2005

510 (k) SUMMARY

Submitter	*Contact*
OBI OsteoBiologics, Inc. 12500 Network, Suite 112 San Antonio, Texas 78249, USA	Gabriele G. Niederauer, Ph.D. Director of Research and Development Phone: 210-690-2131 (ext. 228) Fax: 210-690-2559 E-mail: gabi@obi.com

Date of Summary: November 15, 2004
Common Name: Kit: Bone Void Filler and Bone Graft Delivery Syringe
Proprietary Name: TruGraft™ BGS Syringe
Device Classification: Filler, Calcium Sulfate Preformed Pellets (Product Code MQV) is a Class II device, per 21 CFR 888.3045
510(k) Number:

Description of Device: The TruGraft™ BGS Syringe is a device that can be filled with OsteoBiologics, Inc. products: PolyGraft® BGS or PolyGraft® TCP (K030288 and K033707 respectively) or other bone graft substitute. The TruGraft™ BGS Syringe can be provided as a kit configuration. The convenience kit provides the TruGraft™ BGS Syringe loaded (filled) with a variety of bone graft substitutes.
The TruGraft™ BGS Syringe is a standard piston syringe that consists of a barrel, plunger and removable end cap. The distal end of the barrel is threaded to allow connection to adapters, while without the attachment, the open end allows for filling of the bone graft material. A cap is available to seal the end of the barrel, enclosing the syringe contents. The piston/plunger assembly is used to expel contents or facilitate in the collection into the barrel of the syringe.

Intended Use: The TruGraft™ BGS Syringe is intended for use as a piston syringe for the aspiration of fluids, such as autologous blood, plasma or other blood components. The TruGraft™ Syringe provides the surgeon with a convenient way to mix autologous blood with the PolyGraft® BGS, PolyGraft® TCP or other bone graft substitute and deliver the material to the orthopaedic surgical site. PolyGraft® BGS and PolyGraft® TCP are intended 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® material 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 TruGraft™ BGS Syringe is substantially equivalent in design, function, and performance to the Imbibe™ Bone Marrow Aspiration Syringe [K011087] on Sep 19, 2001, IMBIBE™ II Syringe [K030208] and Vitoss®-Filled Cartridge [K032130].

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 7 2005

Gabriele G. Niederauer, Ph.D.
Director of Research and Development
OsteoBiologics, Inc.
12500 Network, Suite 112
San Antonio, Texas 78249

Re: K043172
Trade/Device Name: TruGraft™ BGS Syringe
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV, FMF
Dated: November 15, 2004
Received: November 26, 2004

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 (240) 276-0120. 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,

for Miriam C. Provost

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

2.4 Indications for Use (Form)

INDICATIONS FOR USE

510(k) Number (if known): K043172

Device Name: TruGraft™ BGS Syringe

Indications For Use:

TruGraft™ BGS Syringe is indicated for the aspiration of fluids, such as autologous blood, plasma or other blood components with preloaded bone graft substitute.

Prescription Use X 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K043172