K041616

AUG 2 5 2004

510(k) Summary - ßGran synthetic osteoconductive scaffold

Prepared & Submitted by:	Orthos (UK) Limited		
Contact Person:	Mr Alan Rorke		
Address:	The Stables, Leigh Court, Abbots Leigh Bristol North Somerset BS8 3RA United Kingdom	Tel: Fax: Email:	+44 1275 376 377 +44 1275 376 378 post@orthos.com

Trade Name	ßGran™ synthetic osteoconductive scaffold	Vitoss™ Scaffold Synthetic Cancellous Bone Void Filler	CerasorbORTHO
510(k) Registration No:		K032409	K014156
Common Name	Resorbable Synthetic Bone Void Filler/Bone Graft Substitute		
Classification Name	Resorbable Calcium Salt Bone Void Filler Device		

Description of the device:

ßGran is a porous, resorbable osteoconductive scaffold constructed of highly pure ß tri-calcium phosphate for use in the repair of bony defects. The material is designed and manufactured to achieve the specification set out in the standard ASTM F 1088-87 (1992) e-1.

The interconnected pores provide a three-dimensional scaffold that mimics the geometry of human cancellous bone matrix. The three-dimensional platform provided by ßGran's osteoconductive scaffold guides the regenerating bone throughout the defect into which it has been implanted. Pore diameters ranging from 1µm to 700µm support re-vascularisation and cellular invasion throughout the matrix

Studies have shown that when ß tri-calcium phosphate is implanted in direct contact with host bone, which has a viable blood supply, that it responds physiologically. Throughout the healing process the matrix resorbs and is replaced by bone and connective tissue. Complete resobption takes between 3 to 12 months

ßGran is supplied as granules, available in three sieve sizes, sterile for single patient use

Intended Use of the Device:

ßGran is intended for use by suitable trained surgical personnel only.

ßGran synthetic osteoconductive scaffold is only intended to be used as a bone void filler for use in the treatment of osseous defects, which can occur as a result of trauma, or in defects created surgically.

ßGran is not intended too and *will not* provide any mechanical stability. It should not therefore be used in osseous defects, which are intrinsic to the stability or integrity of the skeleton without

concurrent treatment to directly address the mechanical stability.

ßGran granules should be gently packed into the bony voids or defects of the skeletal system (i.e., long bones, extremities, spine and pelvis, mandible or maxilla). The granules may be combined with autogenous blood and/or bone marrow. The granules should not be crushed. Following implantation the calcium phosphate matrix will be resorbed and replaced with bone during the healing process.

Comparison to Predicate:

Trade Name	ßGran™ synthetic osteoconductive scaffold	Vitoss™ Scaffold Synthetic Cancellous Bone Void Filler	CerasorbORTHO
510(k) Registration No:		K032409	K014156
Intended Use	The devices intended use is the same as for the Predicate devices. *i.e.* the treatment of osseous defects, which are not intrinsic to the stability or integrity of the skeleton. For complete details please refer to the Intend Use Statement	As a bone void filler for voids or gaps that are not intrinsic to the stability of bone structures. It is indicated for use in the treatment of surgically created osseous defects or osseous defects cause by traumatic injury to the bone.	As a bone void filler for voids or gaps that are not intrinsic to the stability of bone structures. It is indicated for filling of bone defects, caused by surgery, trauma or degenerative process.
Target Population	Individuals with bony defects resulting from surgery or trauma	Individuals with bony defects resulting from surgery or trauma	Patients with bone voids or gaps, caused by surgery, trauma or degeneration
Anatomical Locations	Bony voids or gaps of the skeletal system, i.e., the extremities, spine and pelvis	Bony voids or gaps of the skeletal system, i.e., the extremities, spine and pelvis	skeletal system, (extremities, spine, pelvis)
Labeling	Labeling contains same intended use, contraindications and adverse events as predicate devices	Labeling contains same intended use, contraindications and adverse events as *ßGran synthetic osteoconductive scaffold*	Labeling contains same intended use, contraindications and adverse events as *ßGran synthetic osteoconductive scaffold*
Materials	ß-Tricalcium Phosphate $Ca_3(PO_4)_2$ satisfies ASTM F 1088	ß-Tricalcium Phosphate $Ca_3(PO_4)_2$ satisfies ASTM F 1088	ß-Tricalcium Phosphate $Ca_3(PO_4)_2$
Design			
Physical Structure	Interconnective porosity	Trabecular structure similar to cancellous bone	Interconnective porosity
Porosity	Approximately 70%	Approximately 90%	Approximately 60% to 70%
Pore Size (range)	<1µm - 700µm	1-1000µm	Micropores >0 <80µm
Performance			
Osteoconductivity	Osteoconductive	Osteoconductive	Osteoconductive
Resorption	Complete resorption demonstrated as occurring between 3 and 12 months.	Demonstrated as 76% resorbed at six weeks and 80% at twelve weeks	Resorption reported to occur between 3 and 24 months.

Mechanical Strength	Does not impart mechanical strength to surgical site	Does not impart mechanical strength to surgical site	Granules have no weight bearing capacity. Execution of osteosynthetic measures eventually necessary
Sterility	Sterilized by gamma radiation, single use only	Sterilized by gamma radiation, single use only	Sterilized by gamma radiation, single use only
Biocompatibility	Established	Established	Established
Presentation	Granules in 3 sieve sizes. 250 – 500µm 1 – 2.8 mm 2 – 4 mm	Morsels 1-4mm and Cylinders 9 x 23mm	Granules, and Blocks Granule sizes: 500 - 1000µm 1000 – 2000µm

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 5 2004

Mr. Alan Rorke
Managing Director
Orthos (UK) Limited
The Stables, Leigh Court,
Abbots Leigh
Bristol North Somerset
United Kingdom BS8 3RA

Re: K041616
Trade Name: BGran™ Synthetic Osteoconductive Scaffold
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler
Regulatory Class: II
Product Code: MQV
Dated: June 15, 2004
Received: June 15, 2004

Dear Mr. Rorke

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,

for Mark N. Melkerson

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

510(k) Number (if known): _____

Device Name: ßGran Synthetic Osteoconductive Scaffold

Indications for Use:

ßGran Synthetic Osteoconductive Scaffold Bone Void Filler is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. *ßGran* Scaffold is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone. *ßGran* Scaffold should not be used to treat large defects that in the surgeon's opinion would fail to heal spontaneously.

ßGran Scaffold is intended to be packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis) and may be combined with autogenous blood and/or bone marrow. Following placement in the bony void or gap, the calcium phosphate scaffold resorbs and is replaced with bone during the healing process.

Prescription Use ✗
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

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

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 K041616