K061499

JAN 26 2007

510(k) SUMMARY

OSferion

January 25, 2007

1 General Information

■ Applicant:	Olympus Biomaterial Corporation 34-3 Hirai, Hinode-machi, Nishitama-gun, Tokyo 190-0182, Japan Establishment Registration No: Form 2891 to be submitted to FDA upon 510(k) clearance.
■ Official Correspondent:	Official Correspondent: Laura Storms-Tyler Executive Director Regulatory Affairs & Quality Assurance Olympus America Inc. Two Corporate Center Drive, Melville, NY 11747-9058, USA Phone: 631-844-5688 FAX: 631-844-5554 Email:Laura.storms-tyler@olympus.com Establishment Registration No: 2429304
■ Manufacturer: (Sterilization site)	Olympus Biomaterial Corporation Hinode Factory 34-3 Hirai, Hinode-machi, Nishitama-gun, Tokyo 190-0182. Japan Establishment Registration No: Form 2891 to be submitted to FDA upon 510(k) clearance.

2 Device Identification

■ Device Trade Name:	**OSferion**
■ Common Name:	**Bone void filler**
■ Regulation Number:	**21 CFR 888.3045**
■ Regulation Name:	**Resorbable calcium salt bone void filler device**
■ Regulatory Class:	II
■ Classification Panel:	**Orthopedic**
■ Product Code:	**MQV**

3 Predicate Device Information

Device Name:	**chronOS**	**Vitoss**
Common Name:	**Bone void filler**	**Bone void filler**
Manufacturer:	**Synthes**	**Orthovita**
510(k) No.	**K013072**	**K994337**

4 Device Description

OSferion is a white porous material composed of β-tricalcium phosphate. It is intended to fill bony voids or gaps caused by trauma or surgery that are not intrinsic to the stability of the bony structure. OSferion is used as a bone replacement material and has properties that allow it to be replaced by autogenous bone after implantation.
The OSferion range consists of two product types with porosities of 75% and 60%.
Osferion (porosity:75%) tends to have less compression strength than Osferion (porosity:60%.)
Products are supplied in blocks, cylinders, granules and wedges.

5 Indications for Use

OSferion is indicated to be gently packed or placed into bony voids or gaps of the skeletal system (i.e. the extremities, spine and pelvis,) that are not intrinsic to the stability of the bony structure. Following placement in the bony void or gap, the calcium phosphate scaffold resorbs and is replaced with bone during the healing process.

6 Comparison of Technological Characteristics

OSferion is basically identical to the predicate devices in the indication fir use, and is similar in specifications except for the porosity of the material.
Comparison between the subject and predicate devices is shown in Table1. The clinical literature provided in this submission supports the safety and efficacy of OSferion.

Table 1. Comparison of Specifications
Subject Device: OSferion
Predicate Device: chronOS

Specifications	Subject Device OSferion	Predicate Device Vitoss	Predicate Device chronOS
Indication/Intended use	Bone void filler, synthetic	Bone void filler, synthetic	Bone void filler, synthetic
Patient population	Individuals with bone voids or gaps, caused by surgery or trauma.	Individuals with bone voids or gaps, caused by surgery or trauma.	Individuals with bone voids or gaps, caused by surgery or trauma.
Anatomical location	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	Bony voids or gaps of the skeletal system, i.e., the extremities, spine and pelvis
Labeling	Same intended use, contradictions, warnings, precautions and adverse events as predicate	See enclosure	See enclosure
Structure of the material	Interconnective porosity	Trabecular strucuture similar to cancellous bone	Interconnective porosity
Chemical composition of material	β - Tricalciumphosphate ($CaCO_3$)	β - Tricalciumphosphate ($CaCO_3$)	β - Tricalciumphosphate ($CaCO_3$)
Porosity of material	60%,75%	90%	55%
Sterility	Sterile (High pressure Steam) Single use only	Sterile (gamma radiation) Single use only	Sterile (gamma radiation) Single use only
Biocompatibility	Established	Established	Established
Mechanical strength	Does not impart mechanical strength to surgical site	Does not impart mechanical strength to surgical site	Does not impart mechanical strength to surgical site

7 Conclusion

When compared to the predicate device, this particular device "OSferion" does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Olympus America, Inc.
% Ms. Laura Storms-Tyler
3500 Corporate Parkway
P.O. Box 610
Center Valley, Pennsylvania 18034-0610

JAN 26 2007

Re: K061499
Trade/Device Name: OSferion
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device.
Regulatory Class: Class II
Product Code: MQV
Dated: December 13, 2006
Received: December 26, 2006

Dear Ms. Storms-Tyler:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):

Device Name: **OSferion**

Indications for Use:

OSferion is indicated to be gently packed or placed into bony voids or gaps of the skeletal system (i.e. the extremities, spine and pelvis,) that are not intrinsic to the stability of the bony structure.

Following placement in the bony void or gap, the calcium phosphate scaffold resorbs and is replaced with bone during the healing process.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K061455