K040600

MAY - 7 2004

Exhibit V

510(K) Summary of Safety and Effectiveness

(1) **Submitter's name:** Biocomposites Ltd
Submitter's address: Etruscan Street, Etruria, Stoke-on-Trent, ST1 5PQ, England
Submitter's telephone number: 44 (0) 1782 206500
Contact person: Stephen Bratt
Date summary prepared: 12th February 2004

(2) **Trade or proprietary device name:** Genex® Bone Graft Substitute
Common or usual name: Bone Void Filler, Bone Graft Substitute
Classification name: Resorbable Calcium Salt Bone Void Filler Device, Calcium Sulphate Preformed Pellets

(3) **Legally marketed predicate device:**

Stimulan® Bone Void Filler Kit	Biocomposites Ltd	K021551
Vitoss™ Scaffold	Orthovita Inc	K994337
Therifil™ Bone Void Filler	Therics Inc	K031040
Cem-Ostetic Bone Void Filler	Berkeley Advanced Biomaterials Inc	K022622

(4) **Subject device description:**
Genex® Bone Graft Substitute consists of synthetic bioabsorbable calcium salts, pre-measured mixing solution and tools necessary to mix the components into a paste. These products are provided sterile for singe patient use. When mixed according to directions, the Genex® Bone Graft Substitute produces biodegradable, radiopaque paste/moulded blocks that resorb in approximately 6 – 9 months when used according to labelling.

After the granular powder is hydrated using all of the mixing solution supplied in each pack, the resultant paste can be injected, digitally packed into the bone void to cure *in situ* or moulded into solid implants that are gently paced into non-load bearing voids or gaps of the skeletal system (i.e. the extremities, spine and pelvis). These bone voids may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The implants provide a bone void filler that resorbs and is replaced with bone during the healing process.

(5) **Subject device intended use:**
Genex® is indicated only for bony voids or defects/gaps that are not intrinsic to the stability of the bony structure. Genex® bone graft substitute resultant paste can be injected, digitally packed into the bone void to cure *in situ* or moulded into solid implants that are to be gently packed into the defect. The bony defects or cavities may be surgically created or the result of traumatic injury. Genex® provides a bone graft substitute that resorbs and is replaced with bone during the healing process.

(6) **Technological characteristics:**
Genex® has the same technological characteristics as the predicate devices.

(7) **Performance data:**
Test results confirm that Genex® Bone Graft Substitute provides a bone void filler which, when placed in contact with healthy bone, resorbs and is replaced with bone during the healing process.

(8) **Basis for substantial equivalence:**
Genex® is equivalent in design, materials, intended use, performance indications and contraindications to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 7 2004

Biocomposites Ltd.
J. Stephen Bratt
Managing Director
Etruscan Street, Etruria, Stoke-on-Trent,
Staffordshire, ST1 5PQ, England

Re: K040600
Trade/Device Name: Genex® Bone Graft Substitute
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler
Regulatory Class: II
Product Code: MQV
Dated: March 2, 2004
Received: M arch 8, 2004

Dear Mr. Bratt:

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, PhD, MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040600

Device Name: Genex Bone Graft Substitute

Indications For Use:

Genex® is indicated only for bony voids or defects/gaps that are not intrinsic to the stability of the bony structure.

Genex® bone graft substitute resultant paste can be injected, digitally packed into the bone void to cure *in situ* or moulded into solid implants that are to be gently packed into the defect.

The bony defects or cavities may be surgically created or the result of traumatic injury. Genex® provides a bone graft substitute that resorbs and is replaced with bone during the healing process.

Genex® is provided sterile for single use only.

Prescription Use X 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)

for Mark N Milkerson

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

510(k) Number K040600