AUG 4 2000

Summary of Safety and Effectiveness

K001724

Biocomposites Ltd
Etruscan Street
Etruria
Stoke-on-Trent
ST1 5PQ
England
44 01782 206500

Trade Name: Stimulan™ Calcium Sulfate Bone Void Filler

Common Name: Calcium Sulfate

Classification Name: Unknown

Description: Stimulan™ Calcium Sulfate Bone Void Filler pellets are provided sterile for single patient use. The biodegradable, radiopaque pellets are resorbed in approximately 30-60 days when used in accordance with the device labelling. Stimulan™ is manufactured from 98% medical grade calcium sulfate dihydrate ($CaSO_4 . 2H_2O$) and stearic acid.

Stimulan™ is intended for use in clinical situations where the use of autologous grafts or other bone graft substitutes may be undesirable, due either to the risk of associated infection or unavailability. Stimulan™ is manufactured from medical grade calcium sulfate that resorbs and is replaced with bone during the healing process. Also, as the implant is biodegrable and biocompatible, it may be used at an infected site.

Comparable Features to Predicate Device(s): Features comparable to predicate devices include equivalent design, materials and indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 4 2000

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

Re: K001724
Trade Name: Stimulan Calcium Sulfate Pellets
Regulatory Class: Unclassified
Product Code: MQV
Dated: May 22, 2000
Received: May 26, 2000

Dear Mr. Bratt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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

Stimulan™

Indications For Use

Stimulan™ is intended for use in clinical situations where the use of autologous grafts or other bone graft substitutes may be undesirable, due either to the risk of associated infection or unavailability. Stimulan™ is manufactured from medical grade calcium sulfate that resorbs and is replaced with bone during the healing process. Also, as the implant is biodegradable and biocompatible, it may be used at an infected site.

Dianne R. Vochmer

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001721