K993238

JAN 14 2000

510(k) SUMMARY

SUMMARY OF SAFETY AND EFFECTIVENESS

Fortoss-Cema™

In accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92 Biocomposites Ltd is hereby submitting the 510(k) Summary of Safety and Effectiveness for Fortoss-Cema™.

A. Submitter

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

B. Contact Person

J Stephen Bratt LL.B

C. Date Prepared

22nd September 1999

D. Name of the Device

Fortoss-Cema™

E. Common or Usual Name

Calcium Sulfate Hemihydrate

F. Classification Name

Implant, endosseous for bone filling and/or augmentation

G. Predicate/Legally Marketed Devices

Lifecore Biomedical CapSet™

K993258

H. Device Description

Fortoss-Cema™ is a medical grade calcium sulfate powder and mixing diluent The blended materials form a creamy paste which set to form a barrier over bone graft materials.

I. Intended Use

Fortoss-Cema™ is used as a barrier over bone graft materials to prevent particle migration in an osseous defect.

J. Substantial Equivalence

Fortoss-Cema™ is substantially equivalent in design, function and intended use to the predicate device Lifecore Biomedical CapSet™.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 14 2000

Mr. J.S. Bratt
Managing Director
Biocomposites, Ltd.
Etruscan Street, Etruria, Stroke-on-Trent
Staffordshire, ST1, 5PQ, England

Re: K993238
Trade Name: Fortoss Cema™ Calcium Sulfate Barrier
Regulatory Class: Unclassified
Product Code: LYC
Dated: December 17, 1999
Received: December 20, 1999

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 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 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 (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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4692. 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" (21 CFR 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/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K993238

510(k) Number (if known): K993238

Device Name: Fortoss Cema™

Indications For Use:

Fortoss-Cema™ is a resorbable pre-measured powder which, when blended with the supplied sterile diluent, forms a setting paste.

Fortoss-Cema™ is indicated for use as a barrier in placement over bone graft material to provide a resorbable barrier and prevent particle migration in an osseous defect.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993238