Attachment 3 – 510(k) Summary

JUL 15 2005

Submitter Name:	ACE Surgical Supply Co., Inc.
Submitter Address :	1034 Pearl St., Brockton, MA 02301
Contact Person:	J. Edward Carchidi, DDS
Phone Number:	(508) 588-3100
Fax Number:	(508) 583-3140
Date Prepared:	May 2005
Device Trade Name:	ACE SurgicalPlaster Calcium Sulfate Hemihydrate
Device Common Name:	Calcium Sulfate Hemihydrate
Classification Name:	Bone Filling Augmentation Material, unclassified
Predicate device:	Orthogen Surgiplaster Calcium Sulfate Hemihydrate, K011403
Reason for submission:	Not previously marketed in the USA

Device Description and Materials:
The ACE SurgicalPlaster Calcium Sulfate Hemihydrate is a medical grade calcium sulfate hemihydrate supplied by ClassImplant, s.r.l., distributed by ACE Surgical Supply Co, Inc., intended to be used by itself in bone regenerative techniques.

The ACE SurgicalPlaster Calcium Sulfate Hemihydrate is designed to set-up in vivo. It is mixed with small amounts of regular setting solution to produce a putty-like paste and it is applied on bone defects in overlapping layers. Each layer may then be compressed with a small square of sterile gauze. The last layer may be set using a small square of sterile gauze soaked in the fast setting solution. With time, the resorbing, set ACE SurgicalPlaster Calcium Sulfate Hemihydrate dissolves and recedes leaving behind bioactive calcium phosphate deposits that have been found to stimulate bone in-growth.

Intended Use:
The ACE SurgicalPlaster Calcium Sulfate Hemihydrate is intended to be used by itself in bone regenerative techniques; mixed with other suitable bone filling agents to prevent particle migration in an osseous defect, and, to provide a resorbable barrier over other bone graft material..

Substantial Equivalence/ Device Technological Characteristics and Comparison to Predicate Device(s):
The ACE SurgicalPlaster Calcium Sulfate Hemihydrate is substantially equivalent to the Orthogen SurgiPlaster™ Calcium Sulfate Hemihydrate, K011403.

Among the information and data presented in the 510(k) submission to support the substantial equivalency of the ACE SurgicalPlaster Calcium Sulfate Hemihydrate to the specified predicate device are: 1) device description, 2) indications for use, 3) materials, and 4) labeling. In particular, the information demonstrated there was no difference in the performance, safety, or effectiveness between the ACE SurgicalPlaster Calcium Sulfate Hemihydrate and the specified predicate device.

A3-1A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2005

J. Edward Carchidi, DDS
President
ACE Surgical Supply Company, Incorporated
1034 Pearl Street
Brockton, Massachusetts 02301

Re: K051381
Trade/Device Name: ACE SurgicalPlaster Calicum Sulfate Hemihydrate
Regulation Number: 21 CFR 872.3930
Regulation Name: Tricalcium Phosphate Granules for Dental Bone Repair
Regulatory Class: II
Product Code: LYC
Dated: July 5, 2005
Received: July 6, 2005

Dear Dr. Carchidi:

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.

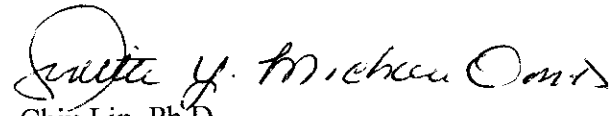
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0115. 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/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ACE Surgical Supply Co., Inc.
1034 Pearl Street
Brockton, MA 02301

Indications for Use

510(k) Number (if known): K051381

Device Name: ACE SurgicalPlaster Calcium Sulfate Hemihydrate

Indications for Use:

The ACE SurgicalPlaster Calcium Sulfate Hemihydrate is intended to be used by itself in bone regenerative techniques; mixed with other suitable bone filling agents to prevent particle migration in an osseous defect, and, to provide a resorbable barrier over other bone graft material.

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)

R.S. Beth DDS for Dr. S. Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K051381