K061462

LDR spine A Passion for Innovation

510(k) Summary

DEC 15 2006

BF+® (Ph) Bone Void Filler

1. **Owner's Name & Address**

LDR Spine USA
4030 West Braker Lane, Suite 360
Austin, TX 78759

Phone: (512) 344-3333
Fax: (512) 344-3350

2. **Contact Person**

James Burrows
Director of Clinical Marketing
LDR Spine USA
4030 West Braker Lane, Suite 360
Austin, TX 78759

Phone: (512) 344-3307
Fax: (512) 344-3350
Email: jamesburrows@ldrspine.com

3. **Date 510(k) Summary Prepared**: November 15, 2006

4. **Trade Name:** BF+® (Ph)
Common Name: Bone Void Filler
Classification: MQV: Filler, Bone Void, Calcium Compound – Class II per 21 CFR 888.3045

5. **Legally Marketed Equivalent Predicate Devices:**
   - K021963 – Sciences et Bio Materiaux (SBM) France BIOSORB® Resorbable Bone Void Filler

6. **Device Description**

The BF+ (Ph) system is manufactured using 100% tricalcium phosphate [$Ca_3(PO_4)_2$]. BF+ (Ph) is a bone graft substitute that resorbs within 6-12 months and is replaced with bone during the healing process.

The identical β tricalcium phosphate (TCP) proposed for use has been used in other legally marked devices within the same classification for the same intended use.

The cube, granule, stick, and block forms are intended to allow for a full range of surgeon preference, and provide a multidirectional interconnected porosity structure similar to that of human cancellous bone. Density for cubes and granules range from 1.228 to 1.842 g/cm^3, and from 1.535 to 1.842 g/cm^3 for sticks and blocks.

7. Intended Use of the Device

BF+ (Ph) resorbable void filler is a resorbable calcium salt bone void filler intended to fill bony voids or gaps of the skeletal system (i.e. the extremities, posterolateral spine and pelvis), caused by trauma or surgery, that are not intrinsic to the stability of the bony structure. BF+ (Ph) is a bone graft substitute that resorbs and is replaced with bone during the healing process.

8. Non-Clinical Performance Data

Mechanical testing of the LDR Spine USA BF+® (Ph) device was not performed, as the materials, processes and supplier are identical to that of the predicate BIOSORB® Resorbable Bone Void Filler manufactured by SBM France (Premarket Notification K021963).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

LDR Spine USA
% Mr. James Burrows
Director of Clinical Marketing
4030 West Braker Lane
Austin, Texas 78759

Re: K061462
Trade/Device Name: BF+® (PH) Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Filler, Bone Void, Calcium Compound
Regulatory Class: Class II
Product Code: MQV
Dated: November 15, 2006
Received: November 17, 2006

DEC 15 2006

Dear Mr. Burrows:

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
Division 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:

Device Name(s): BF+® (Ph) Bone Void Filler

Indications for Use:

BF+ (Ph) resorbable void filler is a resorbable calcium salt bone void filler intended to fill bony voids or gaps of the skeletal system (i.e. the extremities, spine and pelvis), caused by trauma or surgery, that are not intrinsic to the stability of the bony structure.

Prescription Use X OR Over-The-Counter Use ____

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109) (Optional format 1-2-96)

Barbara Buchman

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K061462