OCT 5 2007 K072496

DFine Inc.
3047 Orchard Parkway
San Jose, California 95134

Premarket Notification [510(K)] Summary
(per 21 CFR 807.92)

510(k) number _____

1. Submitted by:

DFine, Inc.
3047 Orchard Parkway
San Jose, CA 95134

Contact Person: Robert D. Poser, DVM
Vice-President, Scientific and Medical Affairs
Telephone: 408-321-9999 ext 224
Facsimile: 408-321-9403

Date Prepared: 31 August 2007

2. Device Name

Trade/Proprietary Name	SPACE CpsXL bone cement
Common/Usual Name	Bone cement for Vertebroplasty
Classification Name	Filler, Bone cement

3. Predicate Device:

The SPACE CpsXL bone cement is substantially equivalent to other bone cements intended for vertebroplasty, including SPACE CpsXL bone cement, cleared under 510(k) K061531 by DFine, Inc. San Jose, CA.

4. Intended use of the device

The SPACE CpsXL bone cement is indicated for the treatment of pathological fractures of the vertebrae using a vertebroplasty or kyphoplasty procedure. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

5. Description of the Device

The SPACE CpsXL bone cement is a self-curing polymethyl-methacrylate (PMMA) bone cement intended for use in the treatment of pathological fractures of the vertebrae using a vertebroplasty or kyphoplasty procedure.

SPACE CpsXL bone cement is provided as a two-component system. The powder component of both devices consists of a PMMA polymer with a barium sulphate as a radiopacifier and benzoyl peroxide as an initiator. The liquid component consists of methylmethacrylate monomer with the addition of hydroquinone as a stabilizer and N,N-dimethyl-p-toluidine as a promoter.

6. Summary of the technological characteristics of the device compared to the predicate device.

Documentation is provided which demonstrated the SPACE CpsXL bone cement to be substantially equivalent to other legally cleared devices. Both the SPACE CpsXL bone cement and the predicate are bone cements intended for use in vertebroplasty, and are similar with respect to chemical composition and fundamental scientific technology. Any differences do not significantly affect the safety and effectiveness of the device.

7. Testing

Physical, chemical and mechanical testing of the SPACE CpsXL bone cement has been conducted.

8. Conclusions

Based upon the testing and comparison to the predicate device and commercially available bone cements, the SPACE CpsXL bone cement, performs as intended and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 5 2007

DFine, Inc.
% Mr. Robert Poser
Vice President, Scientific and Medical Affairs
3047 Orchard Parkway
San Jose, CA 95134

Re: K072496
Trade/Device Name: SPACE CpsXL Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: NDN
Dated: September 1, 2007
Received: September 5, 2007

Dear Mr. Poser:

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.

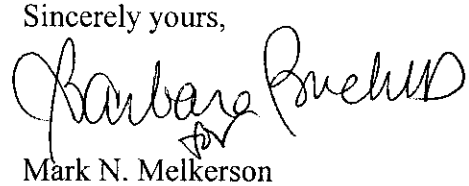
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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 toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known):

Device Name: SPACE CpsXL bone cement

Indications for Use:

The SPACE CpsXL bone cement is indicated for the treatment of pathological fractures of the vertebrae using a vertebroplasty or kyphoplasty procedure. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma) and malignant lesions (metastatic cancers, myeloma).

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bucchi

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

510(k) Number K072496