SPINEWAVE

K063606

APR 13 2007

# 510(k) Summary
# StaXx™ FX System

## Submitter Information

Spine Wave, Inc.
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Shelton, CT 06484
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Contact: Ronald K. Smith
Date Prepared: November 30, 2006

## Device Information

| | |
|---|---|
| Trade name: | StaXx™ FX System |
| Common name: | Internal Fracture Reduction System |
| Classification: | Class II per 21 CFR 888.3027; 21 CFR 888.4540 |
| Classification Name: | Polymethylmethacrylate (PMMA) bone cement; Orthopedic manual surgical instrument |
| Product Code: | NDN; HXG |

## Device Description

The StaXx™ FX System is a vertebral fracture reduction device composed of a base wafer and stackable wafers fabricated from preformed Polyetheretherketone (PEEK-OPTIMA) with 6% Barium Sulfate ($BaSO_4$). The wafers are designed to be inserted incrementally into the vertebral body to form a column that provides the desired fracture reduction. Twenty (20) wafers are provided per package. The wafers are provided in one width (8mm) with three lengths (20mm, 25mm, 30mm).

## Intended Use

The StaXx™ FX System is indicated for use in the reduction of spinal fractures. It is intended to be used in combination with Stryker Spineplex™ Radiopaque Bone Cement.



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## Substantial equivalence[1]

The StaXx™ FX System described in this submission is substantially equivalent to the following device:

| Predicate Device | Manufacturer | 510(k) No. |
|---|---|---|
| StaXx™ FX System | Spine Wave, Inc. | K053336 |

In addition, mechanical testing demonstrated that the StaXx™ FX System meets the performance requirements for its intended use. The minor differences between the StaXx™ FX System and the predicate device do not raise any new questions of safety or effectiveness. Thus, the StaXx™ FX System is substantially equivalent to its predicate device.

[1] *Use of the terms "substantially equivalent" and "substantial equivalence" in this application is intended only to denote a comparison of the subject device to predicate devices for the purpose of an FDA review of the safety and effectiveness of the subject device in accordance with 21 CFR 807. Statements comparing the subject device to predicate devices, including statements regarding "substantial equivalence", contained herein are not intended in any way to relate to patentability, patent infringement, or any analysis of the subject device under foreign or United States patent laws including 35 U.S.C. paragraph 100 et seq. or related judicial doctrines*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Spine Wave, Inc.
% Mr. Ronald Smith
Director, Quality and Regulatory Affairs
Two Enterprise Drive, Suite 302
Shelton, Connecticut 06484

APR 13 2007

Re: K063606
Trade/Device Name: StaXx™ FX System
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: OBL
Dated: February 9, 2007
Received: February 12, 2007

Dear Mr. Smith:

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.

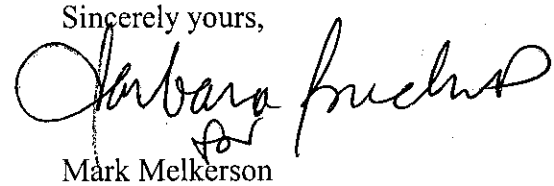
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Melkerson
Director
Division of General, Restorative
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: StaXx™ FX System

Indications for Use:

The StaXx™ FX System is indicated for use in the reduction of spinal fractures. It is intended to be used in combination with Stryker Spineplex™ Radiopaque Bone Cement.

Prescription Use __√____ (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 OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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



**510(k) Number** K063606