

K082017 pay #2

OCT 10 2008

5. 510(k) Summary

Date: June 30, 2008

Company Name: Starr Frame LLC
1302 E. Collins Blvd.
Richardson, TX 75081-2403

Contact Name: Frank Gerome
Starr Frame LLC
(214) 576-9818 (Phone)
(214) 576-9848 (Fax)
fgerome@starrframe.com

Trade Name: Starr Frame Steinmann Pins

Common Name: Bone Fixation Fasteners

Classification Name: Smooth or Threaded Metallic Bone Fixation Fastener

Regulation Number: 888.3040

Product Class: II

Product Code: HTY Pin, Fixation, Smooth
JDW Pin, Fixation, Threaded

Predicate Devices: Depuy Steinmann Pins (K960385)
Teleflex Medical KMedic® Fixation Devices (K070561)
Depuy Steinmann Pins (Pre-amendment)

Device Description: The Starr Frame Steinmann Pins consist of various fixation pins and are offered in assorted dimensions and configurations to accommodate physician preferences, physical profiles of different patients, and varying injuries and conditions. The devices are constructed of implant grade 316LVM stainless steel. They are provided non-sterile and intended for single-use only.

Indications for Use: The Starr Frame Steinmann Pins are non-sterile, single use, fixation devices intended for use in fixation of bone fractures, bone reconstructions, and implantation through the skin so that traction may be applied to the skeletal system.

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**Technological
Characteristics
Comparison:**

The Starr Frame Steinmann Pins are substantially equivalent to the predicate devices with respect to design and material.

**Summary of
Non-Clinical
Performance Data:**

The Starr Frame Steinmann Pins will comply with the following recognized consensus standards: ASTM F366-04 “Standard Specification for Fixation Pins and Wires”; and ISO 5838-1:1995 “Implants for Surgery – Skeletal Pins and Wires – Part 1: Material and Mechanical Requirements”.

Conclusions:

There are no significant differences between the Starr Frame Steinmann Pins and the devices listed as predicate devices. The Starr Frame Steinmann Pins and the predicate devices have similar design attributes, material and intended use and thus are substantially equivalent.



OCT 10 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Starr Frame LLC
% Mr. Frank Gerome
Manager
1302 E. Collins Boulevard
Richardson, Texas 75081

Re: K082017
Trade/Device Name: Starr Frame Steinmann Pins
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY, JDW
Dated: July 15, 2008
Received: July 16, 2008

Dear Mr. Gerome:

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.

Page 2 – Mr. Frank Gerome.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 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

4. Indications for Use Statement

510(k) Number (if known): K082017

Device Name: Starr Frame Steinmann Pins

Indications for Use:

The Starr Frame Steinmann Pins are non-sterile, single use, fixation devices intended for use in fixation of bone fractures, for bone reconstructions, and implantation through the skin so that traction may be applied to the skeletal system.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use Nb
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Dyer, MD

(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

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