510K Summary of Safety and Effectiveness
Fx Devices
Lagwire System

1. Sponsor Name
FxDevices
One South Ocean Blvd., Suite 324
Boca Raton, FL 33432

MAY - 4 2007

2. Device Name
Lagwire System

Panel	Orthopaedic
Classification Name	Smooth or Threaded Metallic Bone Fixation Fastener
CFR Number	Class II (per 21 CFR 888.3040)
Product Code	HWC

3. Identification of Predicate or Legally Marketed Device
The Lagwire is substantially equivalent to the Triage Medical BONE-LOK® MVP Cortical-Cancellous Compression Device cleared under K042244

4. Device Description
The Lagwire fixation system consists of two (2) main components, a wire and a cap. The Lagwire materials are Titanium 6Al-4V alloy, which meets the requirements of ASTM F-136. It is available as 4.5 mm diameter device and is obtainable in various length ranges. The Lagwire is provided sterile and intended for single use only.

5. Intended Use
The Lagwire System is intended for use in the general management of fractures and reconstructive surgery.

6. Comparison of Technological Characteristics
The Lagwire was compared to the predicate with respect to in design, materials, construction, intended use, and performance.

7 Performance Testing
Bench testing was conducted to support equivalency

8. Statement of Equivalency
The Lagwire System is substantially equivalent in design, materials, construction and intended use as those of the predicate device and therefore does not raise any new safety and efficacy concerns when compared to these similar legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FxDevices
% Mr. Rich Lipschutz
Operations Manager
One South Ocean Boulevard
Suite 324
Boca Raton, Florida 33432

MAY - 4 2007

Re: K070393
Trade/Device Name: Lagwire System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: February 6, 2007
Received: February 9, 2007

Dear Mr. Lipschutz:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (PMA), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices 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 devices comply 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 devices as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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
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 (if known): K070393

Device Name: Lagwire System

Indications For Use:

The Lagwire is indicated for use in the general management of fractures and reconstructive surgery.

Prescription Use _X_____ 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)

Barbara Buehrig for MKM

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

510(k) Number K070393