

## 4 510(k) Summary of Safety and Effectiveness

<b>Manufacturer/Distributor/Sponsor</b>	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
<b>510(k) Contact</b>	Sally Foust, RAC Regulatory Affairs Project Manager Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1251 Fax: 239/598.5508 Email: <a href="mailto:sfoust@arthrex.com">sfoust@arthrex.com</a>
<b>Trade Name</b>	Arthrex Compression Staple
<b>Common Name</b>	Fixation Staple
<b>Product Code -Classification Name</b>	JDR – Single/multiple component metallic bone fixation appliances and accessories
<b>Predicate Devices</b>	Wright Medical Compression Staple, K043059
<b>Device Description and Intended Use</b>	<p>The Arthrex Compression Staple is a metal staple offered in five sizes.</p> <p>The Arthrex Compression Staple is intended to be used for fixation such as: LisFranc arthrodesis, mono or bi-cortical osteotomies in the forefoot, first metatarsophalangeal arthrodesis, Akin osteotomy, midfoot and hindfoot arthrodeses or osteotomies, fixation of osteotomies for hallux valgus treatment (Scarf and Chevron), and arthrodesis of the metatarsocuneiform joint to reposition, and stabilize metatarsus primus varus.</p>
<b>Substantial Equivalence Summary</b>	<p>The Arthrex Compression Staple is substantially equivalent to the predicate Wright Medical Compression Staple in which the basic features and intended uses are the same. Any differences between the Arthrex Compression Staple and the predicate Wright Medical Compression Staple are considered minor and do not raise questions concerning safety and effectiveness. Based on the information submitted, Arthrex, Inc. has determined that the new Arthrex Compression Staple is substantially equivalent to the currently marketed predicate device.</p>

FEB 13 2002



FEB 13 2008

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Arthrex, Inc.  
% Sally Foust, RAC  
Regulatory Affairs Project Manager  
1370 Creekside Boulevard  
Naples, Florida 34108-1945

Re: K080111

Trade/Device Name: Compression Staple  
Regulation Number: 21 CFR 888.3030  
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories  
Regulatory Class: II  
Product Code: JDR  
Dated: January 15, 2008  
Received: January 16, 2008

Dear Ms. Foust:

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 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 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

### 3 Indications for Use Form

#### Indications for Use

510(k) Number:                     K080111                    

Device Name:           **Arthrex Compression Staple**          

The Arthrex Compression Staple is intended to be used for fixation such as: LisFranc arthrodesis, mono or bi-cortical osteotomies in the forefoot, first metatarsophalangeal arthrodesis, Akin osteotomy, midfoot and hindfoot arthrodeses or osteotomies, fixation of osteotomies for hallux valgus treatment (Scarf and Chevron), and arthrodesis of the metatarsocuneiform joint to reposition, and stabilize metatarsus primus varus.

Prescription Use   **X**   AND/OR Over-The-Counter Use             
(Per 21 CFR 801 Subpart D)      (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)

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                    Barbara Fruchto                    

**(Division Sign-Off)**

**Division of General, Restorative,  
and Neurological Devices**

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