



Food and Drug Administration  
10903 New Hampshire Avenue  
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Coracoid Solutions, Inc.  
% Michael Kolber  
Consultant, Regulatory Affairs  
Michael Kolber  
337 Ester Ave  
Campbell, California 94025

February 2, 2016

Re: K153211

Trade/Device Name: M-Fix Acromioclavicular Device  
Regulation Number: 21 CFR 888.3030  
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories  
Regulatory Class: Class II  
Product Code: HTN  
Dated: November 4, 2015  
Received: November 5, 2015

Dear Michael Kolber:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Mark N. Melkerson -S**

Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use**510(k) Number (if known): K153211

Device Name: Coracoid Solutions, M-Fix™ Acromioclavicular Device

Indications for Use: The M-Fix™ Acromioclavicular Device is intended to provide fixation during the healing process following syndesmotic trauma such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**510(k) Summary  
(per 21CFR807.92)**

| <b>General Company Information</b>  |  |               |
|---|--|---------------|
| Name:   | Coracoid Solutions, LLC  |               |
| Contact:  | Michael Kolber<br>Regulatory Affairs   |               |
| Address:  | 15 Normans Way<br>Park City, UT 84060  |               |
| Telephone:  | 408-505-6626   |               |
| Fax:  | 408-608-0338   |               |
| Date Prepared:  | November 4, 2015   |               |
| <b>General Device Information</b>   |  |               |
| Product Name:   | M-Fix™ Acromioclavicular Device  |               |
| Common Name:  | Button/Suture  |               |
| Classification Name:  | Washer, Bolt Nut   |               |
| Regulation Number:  | 21CFR888.3030, Single/multiple component metallic bone fixation appliances and accessories |               |
| Device Class:   | Class II   |               |
| Product Code:   | HTN  |               |
| <b>Predicate Devices</b>  |  |               |
| Manufacturer  | Device Name  | 510(k) Number |
| Arthrex, Inc.   | TightRope™ Acromioclavicular (AC) Device   | K052776       |
| Surgicraft, Ltd.  | Lockdown™ Acromioclavicular (AC) Device  | K091207       |
| Dallen Medical, Inc.  | Tensyn™ Band   | K131850       |
| <b>Description</b>  |  |               |
| <p>The M-Fix™ Acromioclavicular Device (M-Fix™) is a suture band system designed to provide reduction and stabilization of the acromioclavicular joint following syndesmotic disruptions. The M-Fix is a polyethylene terephthalate (PET) band that may be tensioned and secured with the integrated, low-profile Connector/Button which is made of titanium or stainless steel.</p> <p>The one-time use band with connector is provided sterile. Additional accessory instruments, including a Counter Traction Tool and a Punch Tool for securing the Connector/Button are single use devices provided sterile for use during the orthopedic procedure.</p> |  |               |
| <b>Intended Use (Indications)</b>   |  |               |
| <p>The M-Fix Acromioclavicular Device is intended to provide fixation during the healing process following syndesmotic trauma such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.</p>   |  |               |
| <b>Substantial Equivalence</b>  |  |               |
| <p>This submission supports the position that the Coracoid Solutions M-Fix is substantially equivalent to the Arthrex TightRope™ Acromioclavicular (AC) Device (K052776), the</p>   |  |               |



Surgicraft Lockdown™ Acromioclavicular (AC) Device (K091207), and the Dallen Medical Tensyn™ Band (K131850). The M-Fix™ has the following similarities to the previously cleared predicate devices: the same or similar intended use, same operating principle, similar technologies, and similar manufacturing process. Design verification activities were performed as a result of the risk analysis. The 510(k) notice contains summaries of bench studies, which were conducted to evaluate the performance characteristics of the M-Fix™. Ultimate Tensile and Cyclic Tests were performed. The information presented demonstrates that the M-Fix™ Acromioclavicular Device is substantially equivalent to the predicate devices.

**Conclusions**

Coracoid Solutions, LLC believes that the information provided demonstrates that the proposed device is substantially equivalent to the predicate devices and does not raise any new issues of safety or efficacy. Based on the indications for use, technological characteristics, and comparison to predicate devices, the M-Fix has been shown to be substantially equivalent to predicate devices as described under the Federal Food, Drug and Cosmetic Act.