SURGICRAFT

FEB 15 2011

510(k) Summary

Contact: Donald W. Guthner
Orgenix, LLC
111 Hill Road
Douglassville, PA 19518
(646) 460-2984

Device Trade Name: *LOCKDOWN™ Acromioclavicular (AC) device.*

Manufacturer: Surgicraft (Trading Name of Mandaco 569 Limited)
16 The Oaks
Clews Road
Redditch, UK
B98 7ST

Classification: 21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories

Class: II

Product Code: HTN

Indications For Use:

The Surgicraft *LOCKDOWN™ Acromioclavicular (AC) device* is indicated to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.

Device Description:

The Surgicraft *LOCKDOWN™ Acromioclavicular (AC) device* is a combination of two FDA-cleared Surgicraft Products, the Surgicraft LOCKDOWN Mesh (K072370) and the Surgicraft LOCKDOWN Screw (K080447). The new product for this indication is designated as the *LOCKDOWN™ Acromioclavicular (AC) device* and will have a new indication to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.

It is not intended that the Surgicraft *LOCKDOWN™ Acromioclavicular (AC) device* be used as the sole means of reconstructing a chronic acromioclavicular joint dislocation.

The *Surgicraft LOCKDOWN Mesh* device is a woven mesh 11mm wide by 4 to 20 cm in length with loops at both ends. The Surgical Mesh is made from braided Polyethyleneterephthalate (Polyester) fibers (PET).

The *Surgicraft LOCKDOWN Screw* is manufactured from stainless steel and titanium alloy. The self-tapping 3.5 mm screws are available in lengths from 14- 40 mm in 1 mm increments. The washers have a hole with an inner diameter of 4.2 mm and an outer diameter ranging from 7 to 9 mm in 1 mm increments.

The Surgicraft *LOCKDOWN™ Acromioclavicular (AC) device* is provided sterile.

Predicate Device(s):

The Surgicraft *LOCKDOWN™ Acromioclavicular (AC) device* was shown to be substantially equivalent to the Arthrex TightRope® Acromioclavicular device (K052776) and has the same indications for use, function and/or materials.

- The Surgicraft *LOCKDOWN™ Acromioclavicular (AC) device* and the named predicate device both use braided Polyethyleneterephthalate (Polyester) fibers (PET), stainless steel and titanium materials to fixate acromioclavicular separations.
- Both devices contraindicate the use of the device as the sole means of reconstructing a chronic acromioclavicular joint dislocation.
- The indications for use statements for both devices are identical.

Performance Standards:

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act applicable to this device. Side-by-side testing was performed with the named predicate device in appropriate cadaver models and indicated that the Surgicraft *LOCKDOWN™ Acromioclavicular (AC) device* is substantially equivalent to predicate device.

Non-Clinical Testing

Mechanical testing was performed on the Surgicraft *LOCKDOWN™ Acromioclavicular (AC) device* or its components prior to submission for approval. Testing performed included biocompatibility testing (per ISO 10993), screw pull-out testing, mesh burst strength and suture attachment strength. In addition, side-by-side testing was performed against the predicate device in an appropriate cadaveric model.

Clinical Testing

No clinical testing was performed nor was deemed necessary to demonstrate substantial equivalence.

Conclusions

Surgicraft considers the *LOCKDOWN™ Acromioclavicular (AC) device* to be equivalent to the predicate device listed above. This conclusion is based upon the devices similarities in function, materials and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Surgicraft, Ltd.
% Mr. Donald W. Guthner
Orgenix, LLC
111 Hill Road
Douglassville, Pennsylvania 19518

FEB 15 2011

Re: K091207
Trade/Device Name: Surgicraft LOCKDOWN™ Acromioclavicular (AC) 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: January 5, 2010
Received: January 6, 2010

Dear Mr. Guthner:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SURGICRAFT

Indications for Use

510(k) Number (if known): K091207

Device Name: **Surgicraft LOCKDOWN™ Acromioclavicular (AC) device**

The Surgicraft *LOCKDOWN™ Acromioclavicular (AC) device* is indicated to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for W. McKarson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091207