JUL 18 2014

Section 5 – 510(k) Summary

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

Submitter Information	
Name	Biomet Manufacturing Corp.
Address	56 East Bell Drive P.O. Box 587 Warsaw, IN 46581
Phone number	(574) 372-1941
Fax number	(574) 371-1027
Establishment Registration Number	1825034
Name of contact person	Jared Cooper Regulatory Affairs Specialist
Date prepared	29 April 2014
Name of device	
Trade or proprietary name	JuggerLoc Bone to Bone System
Common or usual name	Bone Fixation Anchor
Classification Name	Single/multiple component metallic bone fixation appliances and accessories.
Classification panel	Orthopedics
Regulation	21 CFR § 888.3030
Product Code(s)	**HTN** - washer, bolt nut
Legally marketed device(s) to which equivalence is claimed	K130033 – Biomet ToggleLoc System K110145 – Biomet JuggerKnot Soft Anchors K133275 - Arthrex Mini-Tightrope
Reason for 510(k) submission	New Device Construct
Device description	The new JuggerLoc Bone to Bone system is a suture based construct intended to stabilize fractures. The construct consists of a JuggerKnot Soft Anchor with ZipLoop Technology, featuring combinations of suture and metal button fixation.
Indications for use	The JuggerLoc Bone to Bone System is intended for repair in the foot and ankle including indications for: Midfoot repair including but not limited to Lisfranc repair, ankle syndesmosis fixation (syndesmosis disruptions), and as an adjunct in connection with trauma hardware for Weber B and C ankle fractures.
Summary of the Technologies	
The technological characteristics of the JuggerLoc Bone to Bone System are similar to the predicate devices including design, dimensions, function, and materials. The JuggerLoc design differs from the predicate devices by having one soft anchor and one metal button to achieve fixation rather than two metal buttons.	

PERFORMANCE DATA
SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION
Performance Test Summary - New Device
The JuggerLoc Bone to Bone System components have the same basic technological and material characteristics as the predicate devices except for slight modifications to the general design as described in this 510(k) notification. Preclinical performance tests are provided to address the subject construct's strength. A biocompatibility rationale was also provided. Results indicate that the subject construct is substantially equivalent to legally marketed devices.
SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION
Clinical Performance Data/Information: None provided as a basis for substantial equivalence.
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA
The results of preclinical tests and the similarities with legally marketed devices indicate the JuggerLoc Bone to Bone System is substantially equivalent to currently marketed devices. No new concerns of safety or efficacy have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 18, 2014

Biomet Manufacturing Corp.
Dr. Jared Cooper
Regulatory Affairs Specialist
56 East Bell Drive, PO Box 587
Warsaw, Indiana 46581

Re: K141219
Trade/Device Name: JuggerLoc™ Bone to Bone System
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: May 23, 2014
Received: May 27, 2014

Dear Dr. Cooper:

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,

Lori A. Wiggins

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

Enclosure

Section 4 – Indications for Use Statement

510(k) Number: K141219

Device Name: **JuggerLoc™ Bone to Bone System**

Indications For Use:

The Biomet JuggerLoc™ Bone to Bone system is intended for repair in the foot and ankle including indications for:

Midfoot repair including but not limited to Lisfranc repair, ankle syndesmosis fixation (syndesmosis disruptions), and as an adjunct in connection with trauma hardware for Weber B and C ankle fractures.

Prescription Use X AND/OR Over-the-Counter _____
(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)

Elizabeth D Frank -S

Division of Orthopedic Devices