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

Biomet Manufacturing Corp.
Mr. Jared Cooper
Regulatory Affairs Specialist
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

November 19, 2014

Re: K141263
Trade/Device Name: ToggleLoc 2.9 and JuggerLoc Soft Tissue System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDR, MBI
Dated: October 16, 2014
Received: October 17, 2014

Dear Mr. 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,

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): K141263

Device Name: **ToggleLoc 2.9 and JuggerLoc Soft Tissue System**

Indications for Use:

The 2.9 ToggleLoc and JuggerLoc Soft Tissue devices are intended for soft tissue to bone fixation for the following indications:

Shoulder
Bankart lesion repair
SLAP lesion repairs
Acromio-clavicular repair
Capsular shift/capsulolabral reconstruction
Deltoid repair
Rotator cuff tear repair
Biceps Tenodesis

Foot and Ankle
Medial/lateral repair and reconstruction
Mid- and forefoot repair
Hallux valgus reconstruction
Metatarsal ligament/tendon repair or reconstruction
Achilles tendon repair

Elbow
Ulnar or radial collateral ligament reconstruction
Lateral epicondylitis repair
Biceps tendon reattachment

Knee
Extracapsular repair: MCL, LCL, and posterior oblique ligament
Illiotibial band tenodesis
Patellar tendon repair
VMO advancement
Joint capsule closure

Prescription Use ____X___ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Premarket Notification [510(k)] Submission Under 21 CFR § 807.87 for ToggleLoc 2.9 and JuggerLoc Soft Tissue Devices

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the ToggleLoc 2.9 and JuggerLoc Soft Tissue System 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Date: **November 13, 2014**

Submitter:

Biomet Manufacturing Corp.
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Warsaw, IN 46581-0587
Establishment registration number: 1825034

Official Correspondence/Contact Person:

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510(k) Preparer:

Jared Cooper

Product Name:

ToggleLoc 2.9 and JuggerLoc Soft Tissue Devices

Device Classification:

JDR – Staple, Fixation, Bone (21 CFR 888.3030)

MBI – Fastener, Fixation, nondegradable, soft tissue (21 CFR 888.3040)

Legally Marketed Predicates:

Biomet ToggleLoc System (K130033)
Biomet JuggerKnot Soft Anchor (K110145)
Conmed-Linvatec Y-Knot Anchor (K131035)

Device Description:

The JuggerLoc and 2.9 ToggleLoc Soft Tissue System is a non-resorbable system intended to aid in arthroscopic and orthopedic reconstructive procedures requiring soft tissue to bone

Premarket Notification [510(k)] Submission Under 21 CFR § 807.87 for ToggleLoc 2.9 and JuggerLoc Soft Tissue Devices

fixation. The system construct includes various components including; Juggerknot Soft Anchors or ToggleLoc Button with ZipLoop Technology with or without needles. These implants are single use devices and are provided sterile by exposure to Ethylene Oxide.

Intended Use and Indications for Use:

The 2.9 ToggleLoc and JuggerLoc Soft Tissue devices are intended for soft tissue to bone fixation for the following indications:

Shoulder
Bankart lesion repair
SLAP lesion repairs
Acromio-clavicular repair
Capsular shift/capsulolabral reconstruction
Deltoid repair
Rotator cuff tear repair
Biceps Tenodesis

Foot and Ankle
Medial/lateral repair and reconstruction
Mid- and forefoot repair
Hallux valgus reconstruction
Metatarsal ligament/tendon repair or reconstruction
Achilles tendon repair

Elbow
Ulnar or radial collateral ligament reconstruction
Lateral epicondylitis repair
Biceps tendon reattachment

Knee
Extracapsular repair: MCL, LCL, and posterior oblique ligament
Illiotibial band tenodesis
Patellar tendon repair
VMO advancement
Joint capsule closure

Technological Characteristics:

The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use:** The proposed ToggleLoc 2.9 and JuggerLoc Soft Tissue System have the same intended use as the predicate devices for soft tissue to bone fixation.
- **Materials:** The ToggleLoc 2.9 and JuggerLoc Soft Tissue System Implants are manufactured from UHMWPE and Polyester suture and metal button materials as the predicate JuggerKnot and ToggleLoc devices, which include the same manufacturing processess.

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- **Design Features:** The ToggleLoc 2.9 and JuggerLoc Soft Tissue System incorporate the same design features as the predicate devices.
- **Sterilization:** The proposed ToggleLoc 2.9 and JuggerLoc Soft Tissue System are provided sterile via the same sterilization methods for single-use as the predicates.

Performance Data (Nonclinical and/or Clinical):

- Non clinical Tests

  Results from mechanical testing demonstrate the proposed ToggleLoc 2.9 and JuggerLoc Soft Tissue System are substantially equivalent to the predicate devices. No animal or clinical testing was required to support substantial equivalence. A description of the tests and analyses is listed below.
  - Device Insertion testing
  - Cyclic and Static Tensile testing

- Clinical Tests

  Not required for this device.

Conclusions:

The proposed ToggleLoc 2.9 and JuggerLoc Soft Tissue System have similar intended use, technological characteristics, and mechanical performance as the predicate devices. The performance testing data identified no new risks and is substantially equivalent to the legally marketed predicate devices.