January 5, 2018

Biomet Inc.
Kyle Ponce
Regulatory Affairs Associate
56 East Bell Drive
Warsaw, Indiana 46581

Re: K173278
Trade/Device Name: ToggleLoc System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI, JDR
Dated: October 9, 2017
Received: October 13, 2017

Dear Kyle Ponce:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173278

Device Name
ToggleLoc System

Indications for Use *(Describe)*
The ToggleLoc System devices, except the ToggleLoc XL device, 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
Ankle Syndesmosis fixation (Syndesmosis disruptions) and as an adjunct in connection with trauma hardware for Weber B and C ankle fractures (only for ToggleLoc with Tophat/ZipTight Fixation Devices)

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

Knee
ACL/PCL repair / reconstruction
ACL/PCL patellar bone-tendon-bone grafts
Double-Tunnel ACL reconstruction
Extracapsular repair: MCL, LCL, and posterior oblique ligament
Illiotibial band tenodesis
Patellar tendon repair
VMO advancement
Joint capsule closure

Hand and Wrist
Collateral ligament repair
Scapholunate ligament reconstruction
Tendon transfers in phalanx
Volar plate reconstruction

The ToggleLoc XL device is used for fixation of tendons and ligaments during orthopedic reconstruction procedures, such as Anterior Cruciate (ACL) or Posterior Cruciate (PCL) Reconstruction, as well as fixation in cases of unanticipated intraoperative complications, such as cortical breaching.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the ToggleLoc XL 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.

510(k) Number: K173278

Sponsor:
Biomet Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581
Establishment Registration Number: 1825034

Contact Person:
Kyle Ponce
Regulatory Affairs Associate
Telephone: (973)-299-9300 Ext 2125
Fax: (574)-372-1718

Date: October 9, 2017

Subject Device:
Trade Name: ToggleLoc System
Common Name: Soft Tissue Fixation Devices

Classification Name:
- MBI – Fastener, Fixation, Non-Degradable, Soft Tissue (21 CFR 888.3040)
- JDR – Staple, Fixation, Bone (21 CFR 888.3030)

Predicate Device(s):

510(K) Number	Device	Manufacturer
K130033	ToggleLoc System	Biomet, Inc.

Purpose and Device Description:
The ToggleLoc System, including ToggleLoc XL, is a non-resorbable system intended to aid in arthroscopic and orthopedic reconstructive procedures requiring soft tissue fixation due to injury or degenerative disease.

Intended Use and Indications for Use:
The ToggleLoc System devices, except the ToggleLoc XL device, 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
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Hand and Wrist
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The ToggleLoc XL device is used for fixation of tendons and ligaments during orthopedic reconstruction procedures, such as Anterior Cruciate (ACL) or Posterior Cruciate (PCL) Reconstruction, as well as fixation in cases

of unanticipated intraoperative complications, such as cortical breaching.

Summary of Technological Characteristics:

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

- **Intended Use:** Intended use is identical to the predicate devices.
- **Indications for Use:** Indications are similar to the predicate devices. This submission is expanding indications for the ToggleLoc XL.
- **Materials:** Materials are identical to the predicate devices.
- **Design Features:** Design features are identical to the predicate devices.
- **Sterilization:** The proposed ToggleLoc System devices are provided sterile via EtO, the same sterilization method utilized for the predicate devices.

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
  - Non-clinical evaluation demonstrated that the performance of the proposed devices is substantially equivalent to the predicate device in terms of safety and efficacy.
  - Pyrogenicity testing was conducted per ANSI/AAMI/ST72:2011. The results indicate that the biologic endotoxin levels on the ToggleLoc XL devices do not exceed the biologic entodoxin limits stated in ANSI/AAMI/ST72.
- **Clinical Tests:**
  - Clinical data was not required to establish substantial equivalence between the subject ToggleLoc System and the predicate devices.

Substantial Equivalence Conclusion

The proposed ToggleLoc System has similar intended use, technological characteristics, and mechanical performance as the predicate devices. The performance engineering analysis identified no new risks and substantial equivalence to the legally marketed predicate devices.