January 2, 2020

Biomet Inc.
Haley Pioch
Regulatory Affairs Specialist
56 East Bell Drive, PO Box 587
Warsaw, Indiana 46582

Re: K193092
Trade/Device Name: TunneLoc® Tibial Fixation Device
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI, HWC
Dated: November 5, 2019
Received: November 6, 2019

Dear Ms. Pioch:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Laura Rose, Ph.D.
Acting Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193092

Device Name
TunneLoc® Tibial Fixation Device

Indications for Use *(Describe)*
To provide fixation of soft-tissue grafts within the tibial tunnel during anterior cruciate ligament (ACL) and/or posterior cruciate ligament (PCL) reconstruction.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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 TunneLoc Tibial Fixation Device 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 September 13, 2019.

Sponsor:

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

Primary Contact Person:

Haley Pioch
Regulatory Affairs Specialist
Telephone: (412-376-2510 extension 214)

Secondary Contact Person:

Jared Cooper
Regulatory Affairs Manager
Telephone: (574-372-1941)

Date:

November 5, 2019

Subject Device:

Trade Name: TunneLoc® Tibial Fixation Device
Common Name: Soft Tissue Fixation Device

Classification Name:

- MBI– fastener, fixation, nondegradable, soft tissue (21 CFR 888.3040)
- HWC– screw, fixation, bone (21 CFR 888.3040)

Predicate Device(s):

Primary Predicate	510(k) Number
TunneLoc Tibial Fixation Device	K103145

Purpose and Device Description:

The purpose of this submission is:

- To submit a 510(k) for cumulative changes made to the system since original clearance;
  - The subject device includes an updated device naming convention;
  - Modifications made to the subject device inserter to improve ergonomics for the end user, improve surgeon visualization during

implant insertion, and inserter yoke component dimensional modification;
- To update labeling to bring the Instructions for Use up to current practices.

The TunneLoc Tibial Fixation Devices are an implant and inserter instrument system that offers components for treatment of patients that require fixation of soft tissue to bone.

Indications for Use:

To provide fixation of soft-tissue grafts within the tibial tunnel during anterior cruciate ligament (ACL) and/or posterior cruciate ligament (PCL) reconstruction.

Summary of Technological Characteristics:

The rationale for substantial equivalence is based on consideration of the following characteristics:
- **Intended Use:** Identical to predicate
- **Indications for Use:** Identical to predicate
- **Materials:** Identical to predicate
- **Design Features:** Similar to predicate
- **Sterilization:** Identical to predicate

Summary of Performance Data: (Nonclinical and/or Clinical)

Non-Clinical Tests:
- FEA (finite element analysis) and Mechanical Testing supports that the modified tensioning yoke with support ribs demonstrate greater stiffness than the predicate yoke design.
- TunneLoc Assembly Insertion Functional Testing was completed to evaluate functional performance when under simulated use using bone and graft substitutes. Testing demonstrates the tensioner instrument possesses sufficient mechanical strength to support the loads experienced during use and is capable of successfully completing its intended use.
- Bacterial Endotoxins Test (BET) per ANSI/AAMI ST 72:2011 as a part of cleaning validation was performed, demonstrating that the device meets the limit of ≤20 Endotoxin units (EU)/Device per USP41-NF36 Chapter <161> Medical Devices – Bacterial Endotoxin and Pyrogen Tests.

Clinical Tests:
- None provided

Substantial Equivalence

The subject TunneLoc Tibial Fixation Devices have the

Conclusion:

same intended use and indications for use as the predicate devices. The subject devices have similar technological characteristics to the predicates, and the information provided herein demonstrates that:

- any differences do not raise new questions of safety and effectiveness; and
- the subject devices are at least as safe and effective as the legally marketed predicate devices.