September 13, 2019

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

Re: K191459
Trade/Device Name: JuggerStitch Meniscal Repair Device
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: August 12, 2019
Received: August 13, 2019

Dear Mr. 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. 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,

Laurence D. Coyne, Ph.D.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K191459

Device Name
JuggerStitch Meniscal Repair Device

Indications for Use *(Describe)*
The JuggerStitch Meniscal Repair Device is indicated for repair of vertical longitudinal full thickness tears (i.e. bucket-handle) in the red-red and red-white zones. These devices are not to be used for meniscal tears in the avascular zone of the meniscus.

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.

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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 JuggerStitch Meniscal Repair 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 August 12, 2005.

Sponsor:

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

Contact Person:

Kyle Ponce
Regulatory Affairs Specialist
Telephone: (973-299-9300 EXT 2125)
Fax: fax (574-372-1718)

Date:

May 31, 2019

Subject Device:

Trade Name: JuggerStitch Meniscal Repair Device
Common Name: Soft Tissue Fixation Device

Classification Name:

- MBI– Fastener, Fixation, Nondegradable, Soft Tissue (21 CFR 888.3040)

Predicate Device(s):

510(K) Number	Device	Manufacturer
K150424	JuggerStitch Meniscal Repair Device **(Primary Prediate)**	Biomet Sports Medicine
K061776	MaxFire Meniscal Repair Device **(Reference Predicate)**	Biomet Sports Medicine

Purpose and Device Description:

The JuggerStitch Meniscal Repair Device is a permanent fixation anchor system comprised of UHMWPE suture, with two non-resorbable polyester sleeves. The device comes as a unit, pre-assembled on either a Straight or Curved inserter. The purpose of this submission is to introduce modifications to the Juggerstitch suture implant

and inserter for ease of use.

Intended Use and Indications for Use:

The JuggerStitch Meniscal Repair Device is indicated for repair of vertical longitudinal full thickness tears (i.e. bucket-handle) in the red-red and red-white zones. These devices are not to be used for meniscal tears in the avascular zone of the meniscus.

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 identical to the predicate devices.
- **Materials:** Materials are identical to the predicate devices.
- **Design Features:** Design features are similar to the predicate devices.
- **Sterilization:** The proposed JuggerStitch Meniscal Repair Devices are provided sterile via EO, the same sterilization method utilized for the predicate devices.

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
  - Static tensile testing of the JuggerStitch Meniscal Repair Device was performed to verify the strength of the implant. The test results indicate that the device modifications do not introduce any new risks to implant performance.
  - Cantilever bend testing of the JuggerStitch inserter needles was performed to verify the bending strength of the devices. The test results indicate that the device and accessory modifications do not introduce any new risks to needle performance.
  - Tissue penetration force testing of the JuggerStitch inserter needles was performed to verify the penetration force of the devices. The test results indicate that the device and accessory modifications do not introduce any new risks to needle performance.

- Advancement testing of the JuggerStitch depth adjuster was performed to verify the force required to advance the depth adjuster. The test results indicate that the device and accessory modifications do not introduce any new risks to device performance.
- Advancement testing of the JuggerStitch push button was performed to verify the force required to advance the push button. The test results indicate that the device and accessory modifications do not introduce any new risks to device performance.
- A surgeon validation was performed to assess if the JuggerStitch Meniscal Repair Devices meet its intended User Needs. The test results show that the device does perform as intended.
- Sterilization validations were performed on the JuggerStitch Meniscal Repair Devices. The test results show that the devices meet the requirements of ISO 11135 and ISO 11137 as applicable.
- Packaging validations were performed on the packaging configurations of the JuggerStitch Meniscal Repair Devices. The test results show that the devices meet the requirements of ISO 11607.

- **Clinical Tests:**
  - Clinical data was not required to establish substantial equivalence between the subject JuggerStitch Meniscal Device and the predicate devices.

Substantial Equivalence Conclusion

The proposed JuggerStitch Meniscal Repair Devices have been shown to be substantially equivalent to the predicate devices. Results of preclinical tests and the similarities with predicate devices indicate the device will perform within the intended use and no new issues of safety or effectiveness have been raised.