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

February 17, 2017

Biomet Manufacturing Corp.
Mr. Vinay Bhal
Regulatory Affairs Specialist
56 East Bell Drive
PO Box 587
Warsaw, IN 46581

Re: K163651
Trade/Device Name: ExpressBraid Graft Manipulation
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: Class II
Product Code: GAT
Dated: December 22, 2016
Received: December 23, 2016

Dear Mr. Bhal:

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" (21CFR 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,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K163651

Device Name
ExpressBraid Graft Manipulation

Indications for Use *(Describe)*
The ExpressBraid Graft Manipulation is intended for use in soft tissue approximation and/or ligation. The suture may be provided individually or be incorporated as a component, into surgeries where constructs including those with allograft or autograft tissue are used for repair.

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 ExpressBraid Graft Manipulation 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:

Vinay Bhal, PhD
Regulatory Affairs Specialist
Telephone: (574-267-6639)
Fax: (574-267-8137)

Date:

December 22, 2016

Subject Device:

Trade Name: ExpressBraid Graft Manipulation
Common Name: Non-absorbable Surgical Suture

Classification Name:

- GAT– Nonabsorbable poly(ethylene terephthalate) surgical suture (21 CFR 878.5000)

Predicate Device(s):

K152868	ExpressBraid Graft Manipulation	Biomet Inc.

Purpose and Device Description:

This 510(k) submission is necessitated due to the addition of a new contraindication to the IFU for subject device. The new contraindication is:

"ExpressBraid Graft Manipulation is not for use in direct contact with the central nervous system".

The subject device has not changed in any way from previously cleared predicate device in K152868. The subject device consists of a stainless steel, straight needle attached to a strand of MaxBraid suture. The two ends of

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the strand of suture are crimped into the needle. The MaxBraid sutures are braided, non-absorbable sutures available in a white configuration consisting of 100% Ultra High Molecular Weight Polyethylene (UHMWPE) fibers and a blue and white co-braid configuration consisting of Deklene II, Polypropylene suture braided into 100% UHMWPE fibers. The suture is provided uncoated. The colorant used in the blue and white co-braid consists of [phthalocyaninato (2-)] copper <0.5% by weight per 21 CFR Sec. 74.3045.

Intended Use and Indications for Use:

No changes from previously cleared device in K152868. The ExpressBraid Graft Manipulation is intended for use in soft tissue approximation and/or ligation. The suture may be provided individually or be incorporated as a component, into surgeries where constructs including those with allograft or autograft tissue are used for repair.

Summary of Technological Characteristics:

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

- **Intended Use:** Same as cleared in K152868
- **Indications for Use:** Same as cleared in K152868
- **Materials:** Same as cleared in K152868
- **Design Features:** Same as cleared in K152868
- **Sterilization:** Same as cleared in K152868. ExpressBraid Graft Manipulation devices are provided sterile for single-use.

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

- **Non-Clinical Tests:**
  - The performance of ExpressBraid Graft Manipulation device has not changed since its last clearance in K152868 as there are no changes to design, material, or intended use. The performance data submitted in K152868 is still valid and therefore no additional testing was performed.
- **Clinical Tests:**
  - No clinical data are being submitted

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Substantial Equivalence Conclusion	The subject device (ExpressBraid Graft Manipulation) has not changed since its last clearance in K152868 with respect to the intended use, design characteristics, and mechanical performance. Addition of a new contraindication is precautionary and does not introduce any new risks. Therefore the subject device is substantially equivalent to the legally marketed predicate device.