December 19, 2016

Biomet Manufacturing Corp.
Jared Cooper, Ph.D.
Regulatory Affairs Manager
56 East Bell Drive
Po Box 587
Warsaw, Indiana 46581

Re: K160854
Trade/Device Name: MaxBraid™ BroadBand™ Suture and Expressbraid™ Broadband™ Graft Manipulation Suture
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: November 18, 2016
Received: November 22, 2016

Dear Dr. 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,

David Krause -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
Indications for Use

The MaxBraid BroadBand Suture 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.

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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 MaxBraid™ BroadBand™ Suture and Expressbraid™ Broadband™ Graft Manipulation Suture 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 Manufacturing Corp.
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Establishment Registration Number: 1825034

Contact: Jared Cooper, Ph.D
Regulatory Affairs Manager

Date: December 14, 2016

Subject Device: Trade Name: MaxBraid™ BroadBand™ Suture and Expressbraid™ Broadband™ Graft Manipulation Suture

Common Name: Nonabsorbable Surgical Suture

Classification Name:
- GAT—Nonabsorbable poly(ethylene terephthalate) Surgical Suture (21 CFR 878.5000)

Legally marketed devices to which substantial equivalence is claimed:

Predicate Devices: ExpressBraid Graft Manipulation – K152868
Arthrex Fiber Tape Suture (UHMWPE) – K122374

Reference Devices (suture technology): JuggerKnot Soft Anchors – K150768

Device Description

Both MaxBraid BroadBand and Expressbraid Broadband Suture consist of a stainless steel straight or curved needle attached to a strand 1.25mm flat suture with round USP size 1 suture ends or 1.5mm flat suture with round USP size 2 suture ends in 38” lengths. MaxBraid Broadband suture is straight with a single crimped needle, whereas the Expressbraid Broadband suture is a looped construct (both ends crimped into a single needle). The MaxBraid BroadBand Sutures are braided, non-absorbable sutures available in an all blue suture [Chromium-cobalt-aluminum-oxide <2.0% by weight per 21 CFR §73.1015] consisting of Ultra High Molecular Weight Polyethylene (UHMWPE) fibers, a white and green [D&C Green No. 6 per 21 CFR
§74.3206] co-braid configuration consisting of UHMWPE and polyester (PET) fibers, and a white and black [Logwood Extract per §73.1410] co-braid configuration consisting of UHMWPE and nylon. The suture is provided uncoated.

**Intended Use and Indications for Use**

The MaxBraid BroadBand Suture 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 technological characteristics (materials, design, sizing, and indications) of the MaxBraid BroadBand Suture are similar or identical to the predicate devices ExpressBraid Graft Manipulation (K152868) and Arthrex Suture (K122374). Further, JuggerKnot (K150768) incorporates Maxbraid suture which is similar in materials and colorants and has the same manufacturing and processing techniques as the proposed MaxBraid Broadband suture.

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

- **Intended Use**: The MaxBraid BroadBand Suture has the same intended use as the predicate devices, ExpressBraid Graft Manipulation (K152868) and Arthrex Suture (K122374).
- **Indications for Use**: The MaxBraid BroadBand Suture has the same indications for use as the predicate device, ExpressBraid Graft Manipulation (K152868) and Arthrex Suture (K122374)
- **Materials**: MaxBraid BroadBand Suture consists of similar materials as the predicates ExpressBraid Graft Manipulation (K152868) and Arthrex Suture (K122374) with all being manufactured from UHMWPE or co-braids of UHMWPE including polyester, and nylon. The predicate ExpressBraid Graft Manipulation differs by utilizing a co-braid of UHMWPE with polypropylene.
- **USP Reference Standards**: Both MaxBraid BroadBand Suture and ExpressBraid Graft Manipulation (K152868) meet USP Reference Standards except for oversized diameter.
- **Design Features**: Both the MaxBraid BroadBand Suture and the ExpressBraid Graft Manipulation (K152868) are provided with or without needles attached to rounded ends of flat suture. MaxBraid BroadBand Suture is available as a straight configuration, while ExpressBraid Graft Manipulation is available in a looped configuration. This is similar to the Arthrex suture configurations which are supplied sterile, in pre-cut lengths, in various single and multi-loop configurations, and in some cases, with various swaged needles and with stiffened ends.
- **Colorants**: The MaxBraid BroadBand Suture colorants consists of D&C Green No. 6 per 21 CFR §74.3206, Logwood Extract per §73.1410, and Chromium-cobalt-aluminum-oxide <2.0% by weight per 21 CFR §73.1015. These are different than the ExpressBraid Graft Manipulation (K152868) Colorants which consist of phthalocyaninato (-2)] cooper
<0.5% by weight per 21 CFR Sec. 74.3045, and Arthrex Blue Suture (K122374) which uses D&C Blue No. 6.

- **Sterilization**: The MaxBraid BroadBand Suture is provided sterile via Ethylene Oxide, and has the same validation and sterilization method as used for ExpressBraid Graft Manipulation (K152868).

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

MaxBraid BroadBand Suture was tested in accordance with USP – non-absorbable surgical sutures for knot tensile strength, and needle attachment and meets the requirements of the Class II Special Controls Guidance: Surgical Sutures; Guidance for Industry and FDA; June 3, 2003 except for diameter.

Non-clinical substantial equivalence testing for knot tensile strength was performed comparing the MaxBraid BroadBand Suture to the ExpressBraid Graft Manipulation (K152868). Testing concluded that the MaxBraid BroadBand Suture will perform equivalently to the ExpressBraid Graft Manipulation (K152868).

All materials used in MaxBraid BroadBand Suture were evaluated per ISO 10993-1 and meet the standard requirements for biocompatibility.

LAL and Rabbit Implantation testing for pyrogenicity was performed with passing results.

Data from accelerated aging and real time aging evaluations are used to support the proposed shelf life of the Broadband sutures.

**Substantial Equivalence Conclusion**

The proposed MaxBraid BroadBand Suture has the same intended use, similar design characteristics, and similar mechanical performance as the predicate ExpressBraid Graft Manipulation. The performance data identified no new risks and substantial equivalence to the legally marketed predicate device.