June 5, 2018

Arcuro Medical Ltd.
% Ms. Janice Hogan, J.D.
Regulatory Counsel
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, Pennsylvania 19103

Re: K180191
Trade/Device Name: SuperBall Meniscal Repair System
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: March 9, 2018
Received: March 9, 2018

Dear Ms. Hogan:

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 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,

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

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 on last page

510(k) Number *(if known)*

K180191

Device Name

SuperBall Meniscal Repair System

Indications for Use *(Describe)*

The SuperBall Meniscal Repair System is intended for use as a suture retention device to facilitate percutaneous or endoscopic soft tissue procedures such as meniscal repair procedures.

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

Arcuro Medical Ltd.'s SuperBall Meniscal Repair System

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Date Prepared: May 10, 2018

Name of Device: SuperBall Meniscal Repair System

Common or Usual Name: Suture Retention Device

Classification Name: Nonabsorbable poly(ethylene terephthalate) surgical suture

Regulatory Class: II

Product Code and Regulation Number: GAT; 21 CFR 878.5000

Predicate Device: Smith & Nephew, Inc.'s FAST-FIX 360 Meniscal Repair System (K092508)

Reference Device: Genzyme Biosurgery COTTONY II, "silky" I I POLYDEKO & TEVDEKO II Polyester Nonabsorbable Surgical Suture (K021019)
Teleflex Medical Force Fiber® Polyethylene Non-Absorbable Surgical Suture (K063778)

Device Description

The SuperBall Meniscal Repair System is a suture retention device comprised of two non-absorbable, soft suture implants along with a SuperBall securing element preloaded within a curved needle delivery system. More specifically, the device consists of suture bundles, a mesh stitch, actuator suture, pulling suture, and SuperBall securing element.

The SuperBall implants and sutures are composed of polyester and ultra-high molecular weight polyethylene. The system allows for repair procedures in the lateral and medial meniscus, located within the outer 2/3 region of the meniscal zone (i.e., medial and posterior). The structure of the SuperBall is a self-locking structure enabling the SuperBall securing element to remain in its collapsed position. The SuperBall remains secure as the braided component (Mesh) is collapsed from within by pulling the Actuator Suture.

The SuperBall System is provided sterile for single use only.

Intended Use / Indications for Use

The SuperBall Meniscal Repair System is intended for use as a suture retention device to facilitate percutaneous or endoscopic soft tissue procedures such as meniscal repair procedures.

Summary of Technological Characteristics

The SuperBall Meniscal Repair System has very similar technological characteristics to the predicate device. While there are some differences in the technological characteristics of the two devices, these differences do not raise different questions of safety or effectiveness. For example, there are minor differences in materials between the SuperBall and the predicate FAST-FIX 360. The predicate device utilizes polymeric (PEEK) rigid retention implants while the SuperBall retention implants are made of the same materials used for the attached sutures, which are identical for the two devices. Therefore, while there are differences in materials, these differences do not raise new types of safety or effectiveness questions. In both cases, the key questions are whether the implant provides sufficient strength for its intended use and whether it is biocompatible for implantation. Performance testing and biocompatibility testing confirm that the SuperBall materials are appropriate for their intended use, and the differences from the predicate do not adversely impact performance.

Similarly, although there are minor differences in design and dimensions between the devices, these also do not raise any new or different questions of safety or effectiveness. Both devices are “all inside” designs. The FAST-FIX 360 system utilizes two implants that are different in length and width. The SuperBall implants are identical in size and both are within the range of the predicate implants’ size. Both devices also allow the sutures to be cut to length. In both cases, the question of whether the dimensions are appropriate to perform the desired repair remains the same, and performance testing demonstrates that the dimensions are appropriate for the indications for use.

A table comparing the key features of the subject and predicate devices is provided below.

	SuperBall	Smith & Nephew FAST-FIX 360 (K092508)
Description	The SuperBall Meniscal Repair System is an all-inside, all-suture meniscal repair device. Each device includes two non-absorbable, soft suture implants preloaded within a curved needle delivery system along with the SuperBall securing element. The SuperBall System is provided sterile for single use only.	The Smith & Nephew FAST-FIX 360 Meniscal Repair System is an all-inside meniscal repair device. Each device includes two non-absorbable polymer implants, pre-tied with #2-0 non-absorbable suture and pre-loaded into a needle delivery system. The FAST-FIX 360 Meniscal Repair System is provided sterile for single use only.
Intended Use/Indications for Use	The SuperBall Meniscal Repair System is intended for use as a suture retention device to facilitate percutaneous or endoscopic soft tissue procedures such as meniscal repair procedures.	The Smith & Nephew FAST-FIX 360 Meniscal Repair System is intended for use as a suture retention device to facilitate percutaneous or endoscopic soft tissue procedures such as shoulder stabilization (Bankart Repair), rotator cuff repair, meniscal repair and gastrostomy.
Implant Size	L5.60mm x 1.30mm	T1 – L5.08mm x 1.02mm T2 – L4.83mm x 1.50mm
Securing Element	One-way self-locking suture implant (SuperBall) securing element tied with 2 suture bundle implants	One-way self-locking sliding knot tied with 2 suture retention bar implants
Suture Size	Multi strand composition (incorporating suture diameters ranging between USP 2-0 –1)	USP 2-0 (x2) – two sutures (side by side)
Delivery	Sequential delivery using a designated curved needle delivery system and related accessories	Sequential delivery using a designated curved needle delivery system and related accessories
Depth Limiter	Integrated with delivery system	Integrated with delivery system
Depth Adjustment limiter	10mm-18mm from limiter to the tip of the needle	10mm-18mm from limiter to the tip of the needle
How Provided	Sterile, Single Use Only	Sterile, Single Use Only

Performance Data

Comprehensive bench testing has been performed to confirm that the SuperBall has appropriate strength for its intended use and performs in an equivalent manner to the predicate. These tests include the following:

- Verification of dimensional attributes;
- Functional evaluation;
- Evaluation of deployment force;
- Suture knot pull-out;
- Implant and suture detachment force;
- Implant pullout force;
- Cyclic load;
- Corrosion resistance;
- Bond strength.

All tests, including those performed on aged product, confirm that the device performs as intended and has the appropriate physical characteristics and strength for its intended use.

Specifically, suture knot-pull was conducted in accordance with USP-881 – Tensile Strength for the suture strands comprising the SuperBall implant. The results demonstrated compliance with the required limits on average knot-pull tensile strength. Implant and suture detachment force was conducted in accordance with USP-871 – Suture Needle Attachment for the suture strands comprising the SuperBall implant. The results demonstrated compliance with the required limits on Needle Attachment.

A corrosion resistance test was also conducted in accordance to ISO 10555-1:2013, Intravascular catheters — Sterile and single-use catheters, Annex A. The results demonstrated that the devices' stainless steel components are corrosion resistant.

In addition, biocompatibility testing was conducted in accordance with ISO 10993-1:2009 for components that come in direct contact with the patient's body. In all instances, the results demonstrated the biocompatibility of the SuperBall implants and delivery system.

The SuperBall device will be sterilized using a validated EtO sterilization cycle. The EtO sterilization cycles are designed and validated per ISO11135:2014. The maximum residual levels for release purposes of Ethylene Oxide (EtO) and Ethylene Chlorohydrin (EC) are maintained in compliance with the FDA recognized standard ANSI/AAMI/ISO 10993-7: 2008(R) 2012, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals. In addition, package and device stability evaluations were performed to support the proposed shelf life.

Lastly, the device usability was evaluated by surgeons using the device to perform a repair in a silicone model, excised porcine meniscus or cadaver testing. A total of eight surgeons evaluated the usability of the device, with six surgeons evaluating use of the final finished configuration of the device. Users reported that the device was easy to use and no use related risks were reported.

Conclusions

The SuperBall performs in a manner that is substantially equivalent to the predicate FAST-FIX 360. The SuperBall has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended surgical use of the device and do not raise different questions of safety or effectiveness. Thus, the SuperBall is substantially equivalent.