August 10, 2023

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

Re: K223500
Trade/Device Name: SuperBall™ 18º Up, "24º Up" and "12º Reverse" Meniscal Repair Systems
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: July 11, 2023
Received: July 11, 2023

Dear Janice 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. 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,

Jesse Muir -S

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair,
and Trauma Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below

510(k) Number *(if known)*

K223500

Device Name

SuperBall™ “18º-Up”, “24º-Up” and “12º-Reverse” 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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K223500
510(k) SUMMARY

Arcuro Medical Ltd.'s
SuperBall™ 18º Up, "24º Up" and "12º Reverse" Meniscal Repair Systems

Submitter:

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Date Prepared: 11-July-2023

Name of Device: SuperBall™ 18ºUp, "24ºUp" and "12ºReverse" Meniscal Repair Systems

Common or Usual Name: Suture Retention Device

Classification Name per 21CFR878.5000: Nonabsorbable poly(ethylene terephthalate) surgical suture.

Regulatory Class: II

Product Code: GAT

Predicate Device: Arcuro Medical Ltd., SuperBall™ Meniscal Repair System (K180191)

Device Description

The SuperBall™ 18ºUp, "24ºUp" and "12ºReverse" Meniscal Repair System(s) 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. The SuperBall System is provided sterile for single use only.

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).

Intended Use / Indications for Use

The SuperBall™ 18ºUp, "24ºUp" and "12ºReverse" 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.

Technological Characteristics

The SuperBall™ 18ºUp, "24ºUp" and "12ºReverse" Meniscal Repair Systems have near identical technological characteristics to the predicate device. While there are some differences in the technological characteristics of the devices related specifically to ergonomic design and manufacturing processes, these differences do not raise different questions of safety or effectiveness. For example, there are minor differences in materials between the subject devices and the predicate device. The predicate device utilizes polymeric materials used in 3D printing and manual grinding technologies; the subject devices are manufactured utilizing materials that are ideal for injection molding technologies. In addition, the some of the materials comprising the subject devices' implant have been sourced from different suppliers when compared to the predicate device. 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™ 18ºUp, "24ºUp" and "12ºReverse" 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, specifically with the delivery system needle angulation, these also do not raise any new or different questions of safety or effectiveness. All devices are "all inside" designs. All system utilizes two implants that are different in length and width. The subject devices' implants are identical in size and are within the range of the predicate implants' size. All devices also allow the sutures to be cut to length. In all 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™ (K180191)	SuperBall™ 18ºUp, "24ºUp" and "12ºReverse"
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 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.
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 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.
Implant Size	L5.60mm x 1.30mm	L5.60mm x 1.30mm
Securing Element	One-way self-locking suture implant (SuperBall) securing element tied with 2 suture bundle implants	One-way self-locking suture implant (SuperBall) securing element tied with 2 suture bundle implants
Suture Size	Multi strand composition (incorporating suture diameters ranging between USP 2-0 –1)	Multi strand composition (incorporating suture diameters ranging between USP 2-0 –1)
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 by EtO, Single Use Only	Sterile by EtO, Single Use Only

Performance Data

Comprehensive bench testing has been performed to confirm that the SuperBall™ 18ºUp, "24ºUp" and "12ºReverse" have appropriate strength for the stated intended use and perform in an equivalent manner to the predicate. These tests include the following:

- Functional evaluation – Conducted for the verification of the sequential operation of the subject device(s) per the supplied IFU and the proposed mode of operation. These evaluations were conducted upon the subject devices as they were operated throughout routine, sequential operation that results in the deployment of the SuperBall implant in a meniscal simulating material.
- Evaluation of deployment force – Force(s) characterization tests determined the forces applied to the system throughout said sequential operation. These evaluations were conducted upon the subject devices as they were operated throughout routine, sequential operation that results in the deployment of the SuperBall implant in a meniscal simulating material. Each operating step has been evaluated using a designated force measuring gauge suitable for the measuring of the applied force.
- Suture knot-pull - Suture knot-pull was conducted in accordance with USP-881 – Tensile Strength for the suture strands in the implant. The results demonstrated compliance with the required limits on average knot-pull tensile strength.
- Implant and suture detachment force - 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.
- Implant pullout force following Cyclic load – Implant pullout following cyclic load evaluations were conducted to demonstrate that the subject device can withstand cyclical tensile forces and maintain a minimal displacement, as compared to the predicate device under identical loading conditions.
- Corrosion resistance - A corrosion resistance test was conducted in accordance with 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.
- Bond strength - Bonded components detachment tests were conducted to verify that the bonded elements of the subject device(s) delivery system(s) can withstand forces greater than those that may be experienced during clinical use and as derived from the functional evaluations conducted, i.e., the forces required for the sequential operation of the system.

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

The SuperBall™ "18º-Up", "24º-Up" and "12º-Reverse" devices shall be provided sterile by EtO for single use; packaged in a rigid PET-G Blister tray and lid sealed within a Tyvek® pouch.

Validation processes conducted indicated qualified the subject devices' stability throughout transportation and shelf life (storage), verifying that the system complies with predefined specifications and acceptance criteria following a shelf-life period of 2 years (24 months).

Conclusions

The SuperBall™ “18ºUp”, “24ºUp” and “12ºReverse” are as safe and effective as the SuperBall™ device(s). Said share the same intended uses and identical indications, technological characteristics, and principles of operation as its predicate device. The minor differences between the SuperBall™ 18ºUp, “24ºUp” and “12ºReverse” and their predicate device do not alter the intended surgical use of the device and do not raise different questions of safety or effectiveness. Thus, the SuperBall™ 18ºUp, “24ºUp” and “12ºReverse” are substantially equivalent.