February 19, 2025

Arcuro Medical Ltd.
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, Pennsylvania 19103

Re: K244015
Trade/Device Name: SuperBall-RC™
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI, GAT
Dated: December 26, 2024
Received: December 26, 2024

Dear Mrs. 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, MS
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K244015

Device Name

SuperBall-RC™

Indications for Use *(Describe)*

The SuperBall-RC™ System is intended for use as a suture retention device to facilitate percutaneous and endoscopic soft tissue procedures.

The SuperBall-RC™ System is indicated for use in rotator cuff 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) #:

510(k) Summary

Prepared on: 2025-02-13

Contact Details

21 CFR 807.92(a)(1)

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Correspondent Contact	Mrs. Janice Hogan
Correspondent Contact Email	janice.hogan@hoganlovells.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	SuperBall-RC™ 12 degree inserter (SBD-SB-RC-12D); SuperBall-RC™ 18 degree inserter (SBD-SB-RC-18D)
Common Name	Smooth or threaded metallic bone fixation fastener
Classification Name	Fastener, Fixation, Nondegradable, Soft Tissue
Regulation Number	888.3040
Product Code(s)	MBI, GAT

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K221731	FiberStitch™ Implant	MBI
K223500	SuperBall™ Meniscal Repair System	GAT
K131637 (Reference	RMST Staple	GDW

Device Description Summary

21 CFR 807.92(a)(4)

The SuperBall-RC™ System is an all-inside, all-suture repair device.
Each device includes two non-absorbable, soft suture bundles that are attached to each other (USP 1 UHMWPE) and preloaded within a needle delivery system along with the SuperBall securing element made of a braided, coreless sack.
The adjustable depth delivery system insertion needle (available in two, curved needle angles), enables the positioning and subsequent deployment of the two bundles under/within the soft tissue. Once placed, manipulation of the delivery system's trigger tightens the

pulling suture (USP 3-0 Polyester Cottony II Green), thereby approximating the positioned bundles.
The tightened implant is secured by the SuperBall. The SuperBall is passed to nestle beside the deployed bundles. By pulling the SuperBall Actuating suture (USP 2-0 Polyester Tevdek II Green), a ball is formed, securing the implant in position.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The SuperBall-RC™ System is intended for use as a suture retention device to facilitate percutaneous and endoscopic soft tissue procedures.

The SuperBall-RC™ System is indicated for use in rotator cuff repair procedures.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject and predicate (K221731) have the same indications except that the subject device is additionally indicated for percutaneous procedures and the predicate is additionally indicated for use in meniscal procedures. These differences do not alter the intended use of the device.

Technological Comparison

21 CFR 807.92(a)(6)

Comparing the key technological characteristics of the subject SuperBall-RC™ System and the predicate FiberStitch device, the use environment, target user, and patient population of all are identical. The devices are similar in terms of design, materials, and principles of operation in that both are all suture devices. While there are minor differences in design, bench testing has demonstrated equivalent performance.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Shear pullout testing was performed to verify that the SuperBall-RC possesses sufficient mechanical strength given: (1) change in indications and (2) change in implant length. When used in rotator cuff repair procedures, the SuperBall can be used either to (1) perform a primary repair of the tissue or (2) to anchor a repair patch in place. Accordingly, both of the repair configurations were subjected to testing.
Usability testing was performed and all physicians who evaluated the device for the proposed rotator cuff indication indicated that the device is easy for use as no damage was inflicted upon the models (cadaveric shoulder models) and no complications were noted throughout, indicating that the device poses no safety related implications for the additional indication.

Testing demonstrated the SuperBall-RC provides sufficient fixation strength for its intended use.