January 12, 2024

RMR Ortho, LLC
℅ Joe Ritz
Official Correspondent
461 Private Road 4749
Castroville, Texas 78009

Re: K232990
Trade/Device Name: A'TOMIC™ Nitinol Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: JDR
Dated: January 9, 2024
Received: January 9, 2024

Dear Joe Ritz:

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.

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,

Limin Sun -S

Limin Sun, Ph.D.
Assistant Director
DHT6A: Division of Joint
Arthroplasty 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K232990

Device Name

A'TOMIC™ Nitinol Fixation System

Indications for Use *(Describe)*

The A'TOMIC™ Nitinol Fixation System is indicated for use in fracture, osteotomy fixation and joint arthrodesis as well as fixation of bone fragments (i.e., small fragments of bone which are not comminuted to the extent that preclude staple placement). The device is intended for use in short, long, or flat bones. The A'TOMIC Nitinol Fixation System is intended for single use only.

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

Date Prepared: September 21, 2023

The purpose of this submission is to seek clearance for a new device. This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

A. 510(k) Sponsor:

RMR Ortho, LLC
4600 Lockhill Selma Rd., Suite 107
San Antonio, TX 78249

B. Primary Correspondent:

Joe Ritz
President
joe.ritz@blazebiotech.com

C. Premarket Notification:

Trade Name:	A'TOMIC™ Nitinol Fixation System
Common Name:	Staple, Fixation, Bone
Classification Name:	Single/Multiple component metallic bone fixation appliances and accessories
Regulation Number:	21 CFR 888.3030
Product Code:	JDR
Classification:	II

D. Indications for Use:

The A'TOMIC™ Nitinol Fixation System is indicated for use in fracture, osteotomy fixation, and joint arthrodesis as well as fixation of bone fragments (i.e., small fragments of bone which are not comminuted to the extent that preclude staple placement). The device is intended for use in short, long, or flat bones. The A'TOMIC™ Nitinol Fixation System is intended for single use only.

E. Predicate Devices:

The A'TOMIC™ Nitinol Fixation System implant is substantially equivalent to the following devices:

510(k)	Trade Name	Manufacturer
Primary Predicate Device		
K142292	BME Speed™ Implant	BioMedical Enterprises, Inc. (DePuy Synthes)

F. Device Description:

The A'TOMIC™ Nitinol Fixation System, which consists of the A'TOMIC™ Nitinol Fixation System implant and associated instruments, is intended for use for fixation and compression and supports several surgical techniques (e.g., fracture, osteotomy, joint arthrodesis, and fixation of bone fragments). The staples are made of implant-grade Nitinol (ASTM F2063-18) and are designed to exhibit superelastic properties at room temperature. This allows for continued compression to be applied across bone segments, thus enhancing long-term stability, and promoting fusion. Implants are passivated per ASTM F86 following machining to create a surface oxide layer that is resistant to corrosion which ensures the biocompatibility of the implant. Each staple is pre-loaded on an inserter for implantation and sterile packed. The staples are available in multiple sizes, varying by bridge length and leg length, to accommodate individual patient anatomy. Single-use disposable instrumentation is provided to assist in the surgical placement of the A'TOMIC™ Nitinol Fixation System implant. Reusable instrumentation will also be available as an option for the surgeon and facility.

Catalog No.	Description
07.20.1010.21A	A'TOMIC™ 2.0mm NITI IMPLANT 10X10mm 2-LEG, STERILE
07.27.1515.21A	A'TOMIC™ 2.7mm NITI IMPLANT 15X15mm 2-LEG, STERILE
07.27.1818.21A	A'TOMIC™ 2.7mm NITI IMPLANT 18X18mm 2-LEG, STERILE
07.27.2118.21A	A'TOMIC™ 2.7mm NITI IMPLANT 21X18mm 2-LEG, STERILE
07.27.2518.41A	A'TOMIC™ 2.7mm NITI IMPLANT 25X18mm 4-LEG, STERILE
07.32.1518.21A	A'TOMIC™ 3.2mm NITI IMPLANT 15X18mm 2-LEG, STERILE
07.32.1820.21A	A'TOMIC™ 3.2mm NITI IMPLANT 18X20mm 2-LEG, STERILE
07.32.2120.21A	A'TOMIC™ 3.2mm NITI IMPLANT 21X20mm 2-LEG, STERILE
07.32.2520.41A	A'TOMIC™ 3.2mm NITI IMPLANT 25X20mm 4-LEG, STERILE

G. Comparison of Characteristics:

The proposed A'TOMIC™ Nitinol Fixation System implant is substantially equivalent to the predicate, BME Speed™ Implant in material, design, intended use, technological characteristics, product features, and mechanical performance.

	Proposed **A'TOMIC™ Nitinol Fixation System Implant**	**Primary** **BME Speed™ Implant (Predicate cleared under K142292)**	**Proposed vs Primary**
Product Code	JDR	JDR	Same
Regulation #	888.3030	888.3030	Same
Class	II	II	Same
Classification Name	Staple, Fixation, Bone	Staple, Fixation, Bone	Same
Indications for Use	The A'TOMIC™ Nitinol Fixation System is indicated for use in fracture, osteotomy fixation and joint arthrodesis as well as fixation of bone fragments (i.e., small fragments of bone which are not comminuted to the extent that precludes staple placement). The device is intended for use in short, long, or flat bones. The A'TOMIC™ Nitinol Fixation System is intended for single use only.	The Speed™, Speed Shift™, Speed Titan™ and Speed Arc™ are indicated for: • Fracture and osteotomy fixation and joint arthrodesis of the hand and foot. • Fixation of proximal tibial metaphysis osteotomy. • Hand and foot bone fragments, osteotomy fixation and joint arthrodesis. • Fixation of small fragments of bone (i.e., small fragments of bone which are not comminuted to the extent to preclude staple placement). These fragments may be located in long bones such as the femur, fibula and tibia in the lower extremities; the humerus, ulna or radius in the upper extremities; the clavicle and ribs; and in flat bone such as the pelvis, scapula and sternum.	No significant difference.

	Proposed **A'TOMIC™ Nitinol Fixation System Implant**	**Primary** **BME Speed™ Implant (Predicate cleared under K142292)**	**Proposed vs Primary**
Contraindications	• Infection • Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions. • Patient conditions including blood supply limitations, obesity, and insufficient quantity or quality of bone that would impair the ability to securely fix the implant. • Comminuted bone surface that would hinder staple placement. • Foreign body sensitivity to metals. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.	• Comminuted bone surface that would militate against staple placement • Pathologic conditions of bone such as osteopenia that would impair the ability to securely fix the implant • Foreign body sensitivity to metals including nickel. Where material sensitivity is suspected, appropriate tests should be made prior to implantation	No significant difference.
Prescription or OTC?	Prescription	Prescription	Same
Sterility Method	Device Provided Sterile, Sterilized with Gamma Irradiation	Device Provided Sterile, Sterilized with Gamma Irradiation	Same
Sterility Assurance Level (SAL)	$<10^{-6}$	$<10^{-6}$	Same
Packaging of Implant Kits	Packaged with inserter/retention device inside a single sterile barrier pouch.	Packaged with inserter inside a single sterile barrier pouch	No significant difference.

	Proposed **A'TOMIC™ Nitinol Fixation System Implant**	**Primary** **BME Speed™ Implant (Predicate cleared under K142292)**	**Proposed vs Primary**
Implant Material	Nitinol	Nitinol	Same
Additional Instruments Material	Medical Grade Plastic and Stainless Steel	Medical Grade Plastic and Stainless Steel	No significant difference.
Design/Physical Characteristics	Natural arc on the bridge to match the contour of bones, round legs to match profile of drill holes, barbs on legs to increase pullout strength. The staple is constrained in the open position before release into the surgical site.	Natural arc on the bridge to match the contour of bones, squared legs, and barbs on legs to increase pullout strength. The staple is constrained in the open position before release into the surgical site.	No significant difference.

H. Performance Testing:

The proposed A'TOMIC™ Nitinol Fixation System implant was subjected to the following mechanical performance tests to support the assertion of substantial equivalence:

- Static Four Point Bend Testing per ASTM F564-17 (FDA Recognition Number #11-325).
- Static Pull-out Testing per ASTM F564-17 (FDA Recognition Number #11-325).
- Cyclic Corrosion Testing per ASTM F2129-19a (FDA Recognition Number #8-522).
- Pyrogen and Endotoxins Testing per ANSI/AAMI ST72 (FDA Recognition Number #14-541).

The results of this non-clinical testing demonstrate that the mechanical performance of the A'TOMIC™ Nitinol Fixation System implant is sufficient for its intended use and no new questions of safety or efficacy were identified during device testing; therefore, the A'TOMIC™ Nitinol Fixation System implant is considered substantially equivalent to the BME Speed™ predicate device.

I. Conclusions:

The A'TOMIC™ Nitinol Fixation System implant was shown to be substantially equivalent in performance and has the same technological characteristics as the BME Speed™ predicate through comparison in areas including design, intended use, implant materials, product features, mechanical performance, and function. Based on the data submitted, the A'TOMIC™ Nitinol Fixation System implant does not raise any new questions about safety or efficacy. Therefore, it can be concluded that the A'TOMIC™ Nitinol Fixation System implant is substantially equivalent to the predicate device.