Maruho Medical
Sucheta Goyal
Regulatory Affairs Manager
3005 Chastain Meadows Pkwy, suite 300
Marietta, Georgia 30066

Re: K230123
Trade/Device Name: Apollo Knotless Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: March 3, 2023
Received: March 3, 2023

Dear Sucheta Goyal:

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,

Yu-chieh Chiu -S

Digitally signed by Yu-chieh Chiu -S
Date: 2023.05.03 18:57:16 -04'00'

Yu-Chieh Chiu, Ph.D.
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230123

Device Name
Apollo Knotless Suture Anchor

Indications for Use *(Describe)*
The Apollo Knotless Suture Anchors are intended for use in soft tissue to bone fixation in areas such as the shoulder, elbow, knee, hip, wrist, hand, foot, and ankle.

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

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92, a 510(k) summary follows.

510(k) Summary

Apollo Knotless Suture Anchor

Submitter: Maruho Medical
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Contact Person: Sucheta Goyal
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Submission Number: K230123

Date Prepared: Jan 13, 2023

Trade Name: Apollo Knotless Suture Anchor

Device Product Code and Classification
MBI, Class II
Regulation Number: 21 CFR 888.3040
Smooth Or Threaded Metallic Bone Fixation Fastener

Primary Predicate: Apollo and Titan, K133036

Additional Predicate: Apollo Suture Anchor System (K192810) and Argo Knotless SP Anchor (K220757)

Device Description:

The Apollo Knotless Suture Anchors are intended for use in soft tissue to bone fixation in areas such as the shoulder, elbow, knee, hip, wrist, hand, foot, and ankle. The intended patients for the apollo family of suture anchors are the adult general population.
The Apollo Knotless Suture Anchors are made from PEEK (Zeniva ZA-500 and Zeniva ZA-600) per ASTM F2026. The Anchors are provided loaded on individual inserters with and without integrated sutures made of ultra-high molecular weight polyethylene (UHMWPE), sterile, for single use only.

Indications and Intended use:

The Apollo Knotless Suture Anchors are intended for use in soft tissue to bone fixation in areas such as the shoulder, elbow, knee, hip, wrist, hand, foot, and ankle.

Comparison of Technological Characteristics with The Predicate Device:

The subject and predicate devices have similar technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. The following characteristics are identical between the subject device and predicate devices:

- Fundamental technology
- Principle of operation
- Technological characteristics (material, sterilization)

Modifications to the Delivery Device are the following:

- Modify the existing handle to have all the working features internal to the device. Remove the stainless inner shaft from protruding outside the over-molded handle body and replace it with a rotating proximal knob locking mechanism.
- Update product colors to reflect the Maruho brand; colors are based on anchor diameter size.
- Update Stainless Steel material from 316 SS to 17-4 SS on the inner shaft component to increase material hardness. Raw material suppliers remain unchanged.

Therefore, there are no significant differences in technological characteristics compared to the predicate. Maruho Medical concluded that the candidate device is substantially equivalent to the predicate device.

Summary of Performance Testing:

The Apollo Knotless Suture Anchor meets requirements and is tested per predicate device K133036 performance. FDA Guidance "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA" was followed during the preparation of this submission. Materials used were evaluated per ISO 10993-1:2009 – Biological Evaluation of Medical Devices. The Apollo Knotless Suture Anchor is sterilized using Ethylene Oxide process to achieve a minimum sterility Assurance Level (SAL) of 10^{-6} following ISO 11135. Limulus Amebocyte Lysate (LAL) endotoxin quantification assessments, both process validation and routine testing, demonstrate endotoxin quantities below the recommended limits outlined in FDA Guidance "Pyrogens and Endotoxins Testing: Questions and Answers."

Performance testing included axial pullout, insertion torque, and torque to failure tests per ASTM F543-07. Dynamic pullout/fatigue tests were also performed. Side-by-side testing to predicate devices was completed with test results demonstrating that the Apollo Suture Anchor Systems are substantially equivalent to the predicate devices.

Substantial Equivalence and Comparison of Technical Characteristics:

The Apollo Knotless Suture Anchor is substantially equivalent to the predicate devices. The Apollo Knotless Suture Anchor has a similar intended use, and indications for use as the predicate device cleared per K220775. The Apollo Knotless Suture Anchor also has similar principles of operation and similar technical characteristics as the predicate device Apollo cleared per K192810. Both the Apollo Knotless Suture Anchor and the predicate devices are sterilized using the same processes, are composed of the same material, and demonstrated the same performance. Therefore, the Apollo Knotless Suture Anchor is substantially equivalent to the currently marketed predicate device.

Conclusion:

Based on the performance testing and the similarities of the indications for use and the technological characteristics, it can be concluded that the Apollo Knotless Suture Anchor is as safe and effective as, and substantially equivalent to, the predicate devices.