Ascension Orthopedics, Inc.
Omunique Luke
Regulatory Affairs Specialist II
11101 Metric Blvd
Austin, Texas 78758

December 14, 2023

Re: K233670
Trade/Device Name: Ascension Silicone MCP; Ascension Silicone PIP
Regulation Number: 21 CFR 888.3230
Regulation Name: Finger joint polymer constrained prosthesis
Regulatory Class: Class II
Product Code: KYJ
Dated: November 15, 2023
Received: November 15, 2023

Dear Omunique Luke:

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,

Joseph P. Russell -S

Digitally signed by Joseph P. Russell -S
Date: 2023.12.14 10:56:54 -05'00'

for: Farzana Sharmin, PhD
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233670

Device Name

Ascension Silicone MCP;
Ascension Silicone PIP

Indications for Use *(Describe)*

The ASCENSION Silicone PIP implant is intended for cementless replacement of the proximal interphalangeal joint in patients with advanced osteoarthritis, post-traumatic arthritis and rheumatoid arthritis.

The ASCENSION Silicone MCP implant is intended for cementless replacement of the metacarpophalangeal (MCP) joint of the finger where disabled by rheumatoid, degenerative or traumatic arthritis.

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

Silicone Implant MR Safe Labeling Special 510(K)

Sponsor	Ascension Orthopedics, Inc. 11101 Metric Blvd. Austin, TX 78758
Establishment Number	3014207283
Point of Contact	Omunique (Nikki) Luke Regulatory Affairs Specialist 512-964-2309
Date	November 15, 2023
Trade Name(s)	Ascension Silicone MCP Ascension Silicone PIP
Common Name	Finger Prosthesis
Product Code	KYJ
Regulation	888.3230 - Finger joint polymer constrained prosthesis
Classification	Class II
Primary Predicate Device	Ascension Silicone MCP: K022892
Additional Predicate Device	Ascension Silicone PIP: K082231
Review Branch	Orthopedic
Device Description	The ASCENSION Silicone MCP and PIP implants are anatomically designed, single-use, one-piece, flexible hinge prostheses designed to be implanted without bone cement across the metacarpophalangeal (MCP) joint and proximal interphalangeal (PIP) joint. They are made from medical grade silicone elastomer. The proximal and distal stems of the prostheses are pre-flexed to match the approximate natural flexion position of the joint when the hand is relaxed. The MCP and PIP implants provide 90 degrees of flexion from full extension.
Intended Use/Indications for Use	The ASCENSION Silicone PIP implant is intended for cementless replacement of the proximal interphalangeal joint in patients with advanced osteoarthritis, post-traumatic arthritis and rheumatoid arthritis. The ASCENSION Silicone MCP implant is intended for cementless replacement of the metacarpophalangeal (MCP) joint of the finger where disabled by rheumatoid, degenerative or traumatic arthritis.
Technological Characteristics	The purpose of this submission is the addition of MR Safe Labeling to the subject devices. There are no other changes proposed in this submission. The following aspects of the devices are not impacted by the additional labeling and remain equivalent to the predicate devices as cleared in their respective 510(k)s. • Intended Use / Indications for Use • Contraindications • Warnings and Precautions • Design • Performance Specifications • Materials • Biocompatibility • Sterilization and Shelf life

Nonclinical Performance Data	Safety and compatibility in the magnetic resonance (MR) environment were established through a scientific rationale that addressed information about the electrical conductivity and magnetic properties of the device material per the FDA guidance document “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment.” In accordance with the terminology in ASTM F2503-20, the Ascension Silicone MCP and Ascension Silicone PIP implant systems are considered MR Safe. Non-clinical performance data is not required to support the addition of MR Safe labeling to the subject devices.
Conclusion	The Ascension Silicone MCP and Ascension Silicone PIP system implants are comprised of medical-grade silicone, a non-magnetic and non-electrically conductive material. Based on the analysis of silicone, the silicone material (and, therefore, devices comprised solely of silicone) is not expected to exhibit any significant or unsafe interactions with the MR environment.