October 21, 2019

Fusion Orthopedics, LLC
Eli Jacobson
Official Correspondent
4135 S. Power Rd., Suite 110
Mesa, Arizona 85212

Re: K190136
Trade/Device Name: Fusion Silastic System
Regulation Number: 21 CFR 888.3720
Regulation Name: Toe joint polymer constrained prosthesis
Regulatory Class: Class II
Product Code: KWH
Dated: September 18, 2019
Received: September 20, 2019

Dear Eli Jacobson:

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,

For Ting Song
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190136

Device Name

Fusion Silastic System

Indications for Use *(Describe)*

The GAIT Implants are intended for patients presenting with class 3 degeneration of the first metatarsophalangeal joint with narrowing of the joint space, loss of joint cartilage, bony spur ring surrounding the joint space, and a painful range of motion of the first metatarsophalangeal joint both with rotation and with walking. This application is not expected to recreate a normal range of motion of the first metatarsophalangeal joint. The GAIT Implant is a spacer that augments the Keller arthroplasty procedure by stabilizing the hallux to the first metatarsal.

The GAIT Implants w/Grommets are intended for patients presenting with class 3 degeneration of the first metatarsophalangeal joint with narrowing of the joint space, loss of joint cartilage, bony spur ring surrounding the joint space, and a painful range of motion of the first metatarsophalangeal joint both with rotation and with walking. This application is not expected to recreate a normal range of motion of the first metatarsophalangeal joint. The GAIT Implant is a spacer that augments the Keller arthroplasty procedure by stabilizing the hallux to the first metatarsal.

The GAIT 2.0 Implants are intended for patients presenting with class 3 degeneration of the first metatarsophalangeal joint with narrowing of the joint space, loss of joint cartilage, bony spur ring surrounding the joint space, and a painful range of motion of the first metatarsophalangeal joint both with rotation and with walking. This application is not expected to recreate a normal range of motion of the first metatarsophalangeal joint. The GAIT Implant is a spacer that augments the Keller arthroplasty procedure by stabilizing the hallux to the first metatarsal.

The GAIT 2.0 Implants w/Grommets are intended for patients presenting with class 3 degeneration of the first metatarsophalangeal joint with narrowing of the joint space, loss of joint cartilage, bony spur ring surrounding the joint space, and a painful range of motion of the first metatarsophalangeal joint both with rotation and with walking. This application is not expected to recreate a normal range of motion of the first metatarsophalangeal joint. The GAIT Implant is a spacer that augments the Keller arthroplasty procedure by stabilizing the hallux to the first metatarsal.

The SHIP Long Implants, are intended for patients presenting with the following indications commonly found in the interphalangeal joints: Semi-rigid or rigid hammertoe deformity; Angular deformity; Impaired function and stability; Pain; Impaired toe length ratio.

The Shaw Rod Implant is intended for patients presenting with the following indications commonly found in the interphalangeal joints: Semi-rigid or rigid hammertoe deformity; Angular deformity; Impaired function and stability; Pain; Impaired toe length ratio.

The SHIP Short Implants are intended for patients presenting with the following indications commonly found in the interphalangeal joints: Semi-rigid or rigid hammertoe deformity; Angular deformity; Impaired function and stability; Pain; Impaired toe length ratio.

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.

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510(k) Summary: Fusion Silastic System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

Date Prepared	January 28, 2019
Submitted By	Fusion Orthopedics, LLC 4135 S. Power Rd., Suite 110 Mesa, AZ 85212 800-403-6876
Primary Contact	Eli Jacobson 4135 S. Power Rd., Suite 110 Mesa, AZ 85212 800-403-6876 Tele e-mail: eli@fusionorthopedics.com
Trade Name	Fusion Silastic System
Common Name	Prosthesis, Toe, Constrained, Polymer
Class	II
Product Code	KWH
CFR Section	21 CFR Section 888.3720
Device Panel	Orthopedic
Primary Predicate Device	Sgarlato Flexible Hinge Toe Implant (K905795) Sgarlato Lesser Toe Implant (K884739) ORTHOFLEX: Silicone Hammertoe Implant (K102601)
Secondary Predicate Device	RTS Flexible 1 MPJ Implant W/Grommets (K153609)
Device Description	The Fusion Silastic System consists of a collection of flexible toe joint prostheses, manufactured from medical grade silicone (ASTM F2042). The product family is offered in five configurations to address varying indications and patient anatomy; the Gait Implant, the Gait 2.0 Implant, the SHIP Long Implant, the SHIP Short Implant and the Shaw Rod. The specialized instruments are made primarily of surgical grade stainless steel (ASTM F899).
Indications for Use	The GAIT Implants are intended for patients presenting with class 3 degeneration of the first metatarsophalangeal joint with narrowing of the joint space, loss of joint cartilage, bony spur ring surrounding the joint space, and a painful range of motion of the first metatarsophalangeal joint both with rotation and with walking. This application is not expected to recreate a normal range of motion of the first metatarsophalangeal joint. The GAIT Implant is a spacer that augments the Keller arthroplasty procedure by stabilizing the hallux to the first metatarsal. The GAIT 2.0 Implants are intended for patients presenting with class 3 degeneration of the first metatarsophalangeal joint with narrowing of the joint space, loss of joint cartilage, bony spur ring surrounding the joint space, and a painful range of motion of the first metatarsophalangeal joint both with rotation and with walking. This application is not expected to recreate a normal range of motion of the first metatarsophalangeal joint. The GAIT Implant is a spacer that augments the Keller arthroplasty procedure by stabilizing the hallux to the first metatarsal.

	The GAIT Implants w/Grommets are intended for patients presenting with class 3 degeneration of the first metatarsophalangeal joint with narrowing of the joint space, loss of joint cartilage, bony spur ring surrounding the joint space, and a painful range of motion of the first metatarsophalangeal joint both with rotation and with walking. This application is not expected to recreate a normal range of motion of the first metatarsophalangeal joint. The GAIT Implant is a spacer that augments the Keller arthroplasty procedure by stabilizing the hallux to the first metatarsal. The GAIT 2.0 Implants w/Grommets are intended for patients presenting with class 3 degeneration of the first metatarsophalangeal joint with narrowing of the joint space, loss of joint cartilage, bony spur ring surrounding the joint space, and a painful range of motion of the first metatarsophalangeal joint both with rotation and with walking. This application is not expected to recreate a normal range of motion of the first metatarsophalangeal joint. The GAIT Implant is a spacer that augments the Keller arthroplasty procedure by stabilizing the hallux to the first metatarsal. The SHIP Long Implants are intended for patients presenting with the following indications commonly found in the interphalangeal joints: Semi-rigid or rigid hammertoe deformity; Angular deformity; Impaired function and stability; Pain; Impaired toe length ratio. The Shaw Rod Implants are intended for patients presenting with the following indications commonly found in the interphalangeal joints: Semi-rigid or rigid hammertoe deformity; Angular deformity; Impaired function and stability; Pain; Impaired toe length ratio. The SHIP Short Implants are intended for patients presenting with the following indications commonly found in the interphalangeal joints: Semi-rigid or rigid hammertoe deformity; Angular deformity; Impaired function and stability; Pain; Impaired toe length ratio.
Materials	Stainless steel (ASTM F899) Silicone (ASTM F20242 and ASTM F2038) Pure Titanium (ASTM F67-13)
Substantial Equivalence Claimed to Predicate Devices	The Fusion Silastic System is substantially equivalent to the predicate devices in terms of design, materials used, mechanical safety and performances.
Non-clinical Test Summary	Validations were performed on the cleaning, packaging and sterilization of the implants and associated surgical instruments. Engineering rational was performed to show performance equivalence. The results of the testing demonstrate that the device is substantially equivalent to the predicate device identified above.
Clinical Test Summary	No clinical studies were performed
Conclusions: Non- clinical and Clinical	Fusion Orthopedics LLC considers the Fusion Silastic System to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.