October 29, 2026

Keri Medical SA
% Sarah Pleaugh
Director, Regulatory Affairs
MCRA, LLC
803 7th St. NW
Washington, District of Columbia 20001

Re: K263582
Trade/Device Name: KeriFlex® MCP and PIP Finger Joint Prostheses
Regulation Number: 21 CFR 888.3230
Regulation Name: Finger joint polymer constrained prosthesis
Regulatory Class: Class II
Product Code: KYJ
Dated: September 30, 2026
Received: September 30, 2026

Dear Sarah Pleaugh:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

FARZANA SHARMIN -S

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K263582

Please provide the device trade name(s).

KeriFlex® MCP and PIP Finger Joint Prostheses

Please provide your Indications for Use below.

The KeriFlex® MCP and KeriFlex® PIP Finger Joint Prostheses are indicated for cementless replacement of the metacarpophalangeal (MCP) and interphalangeal (PIP) joints, respectively, where disabled by rheumatoid, degenerative or traumatic arthritis.

Please select the types of uses.

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [ ] Adolescents (12 years old to < 22 years old)
- [x] Adults (22 years old and greater)

510(k) Summary

Device Trade Name:	KeriFlex® MCP and PIP Finger Joint Prostheses
Manufacturer:	KERI MEDICAL SA Chemin du Pré-Fleuri, 5 1228 Plan-les-Ouates Switzerland
Contact:	Camille Miletto Regulatory Affairs Manager KERI MEDICAL SA Chemin du Pré-Fleuri, 5 1228 Plan-les-Ouates Switzerland Phone: +41 582 550 149
	Sarah Pleaugh Director (SME), Regulatory Affairs MCRA LLC 803 7th St NW Washington DC 20001 USA Phone: 1(201) 728-0032
Date Prepared:	September 30th, 2026
Panel:	Orthopedic
Class:	II
Product Code:	KYJ
Regulation Name:	Finger joint polymer constrained prosthesis
Regulation Number:	888.3230
Predicate Device:	KeriFlex® MCP and PIP Finger Joint Prostheses (K211385)

Indications For Use:

The KeriFlex® MCP and KeriFlex® PIP Finger Joint Prostheses are indicated for cementless replacement of the metacarpophalangeal (MCP) and interphalangeal (PIP) joints, respectively, where disabled by rheumatoid, degenerative or traumatic arthritis.

Device Description:

The KeriFlex® Finger Joint Prostheses are flexible, one-piece, hinged silicone elastomer implants designed to be implanted across the metacarpophalangeal (MCP) or proximal interphalangeal (PIP) joints. The proximal and distal stems of the prosthesis form an angle, which mimics the approximate position of the joint when the hand is relaxed.

The KeriFlex® Finger Joint Prostheses are single-use devices indicated for cementless replacement of the metacarpophalangeal (MCP) and interphalangeal (PIP) joints, respectively, where disabled by rheumatoid, degenerative or traumatic arthritis. The KeriFlex® Finger Prostheses are provided sterile and are intended to be single use.

The associated instruments include:

- Patterns to be used prior to the bone cut to identify the resection level and to identify the definitive implant.
- Starter (awl) to help the surgeon prepare the implantation site.
- Rasps to help the surgeon prepare the implantation site.
- Sterilization tray and lid which protect the instruments during transportation and sterilization.

The purpose of this submission is to add a new smallest PIP prosthesis size.

Comparison of Technological Characteristics:

The subject device and the predicate device both have the same intended use, principle of operation, fundamental design concept, materials, and method of implantation. Both devices function as passive mechanical finger joint prostheses and do not require an external energy source.

The only technological difference addressed by this Special 510(k) is the dimensional configuration of the subject device, which is the new smallest size within the existing device family. The differences in design do not affect device safety and effectiveness and the performance testing conducted demonstrates substantial equivalence.

Performance Testing Summary:

The following performance testing was performed on the new smallest KeriFlex® PIP device:

- Fatigue test
- Range of motion verification

Conclusion:

Based on the indications for use, technological characteristics, performance testing and comparison to the predicate device, the subject device is substantially equivalent to the legally marketed predicate device.