Keri Medical SA
Bernard Prandi
President
Route des Acacias, 45a
Geneva, CH-1227
Switzerland

July 27, 2022

Re: K211385
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: June 24, 2022
Received: June 24, 2022

Dear Bernard Prandi:

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 Jiping Chen, MD, Ph.D., M.P.H.
Acting Division 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.

510(k) Number *(if known)*
K211385

Device Name
KeriFlex® MCP and PIP Finger Joint Prostheses

Indications for Use *(Describe)*
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.

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

Device Trade Name:	KeriFlex® MCP and PIP Finger Joint Prostheses
Manufacturer:	Keri Medical SA Route des Acacias, 45a CH-1227 Geneva Switzerland
Contact:	Bernard Prandi President +41 58 255 01 30
Prepared by:	Mehdi Kazemzadeh-Narbat, PhD, PMP, CQA Associate Director, Regulatory Affairs MCRA, LLC 803 7th, Street NW, Floor 3 Washington, DC 20001 Office: 202.552.6011 mkazemzadeh@mcra.com
Date Prepared:	July 27, 2022
Classifications:	Finger Joint Polymer Constrained Prosthesis, under 21 CFR 888.3230
Class:	II
Product Code:	KYJ
Predicate Devices:	DePuy Orthopaedics' NeuFlex PIP Finger Joint Prosthesis (K083107) DePuy Orthopaedics' MCP Finger Joint Prosthesis (K970544)

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, lid, insert and rack which protect the instruments during transportation and sterilization.

Comparison of Technological Characteristics:
The subject and predicate devices have the same intended use, have similar technological characteristics and geometries, and are made of similar materials.

Device		**MCP Finger Joint Prosthesis (K970544)**	**NeuFlex PIP Finger Joint Prosthesis (K083107)**	**Subject Device (KERIFLEX®)**
Manufacturers		**DEPUY INC.**	**DEPUY INC.**	**KERIMEDICAL**
Regulation CFR classification		888.3230		
Product code		KYJ		
Indication for use		The DePuy DuPont Orthopaedics Finger Joint Prosthesis is indicated for cementless replacement of the metacarpophalangeal (MCP) joints of the finger where disabled by rheumatoid, degenerative or traumatic arthritis	The DePuy DuPont Orthopaedics Finger Joint Prosthesis is indicated for cementless replacement of the proximal interphalangeal (PIP) joints of the finger where disabled by rheumatoid, degenerative or traumatic arthritis	The KeriFlex® Finger Joint Prostheses are devices indicated for cementless replacement of the metacarpophalangeal (MCP) and interphalangeal (PIP) joints, respectively, where disabled by rheumatoid, degenerative or traumatic arthritis.
Design	**Material**	Silicone elastomer		
	Sizes	12 sizes 5 implants for the interphalangeal (PIP) 7 implants for metacarpo-phalangeal (MCP)		
	Angle (°)	30°C for MCP	15° for PIP	30°C for MCP and 15° for PIP
Ancillaries	**Material**	Silicone Elastomer		

	Sizer	12 sizes 5 implants for the interphalangeal (PIP) 7 implants for metacarpo-phalangeal (MCP)	
Sterility		Sterile (Plasma Gas)	Sterile (ETO)
Single-Use		Yes	
Shelf Life		5 years	

Performance Data:
The following performance testing was performed on the KeriFlex® devices:

- Fatigue Test
- Material Characterization
- Range of Motion

Conclusion:
The subject and predicate devices have the same intended use, have similar technological characteristics and geometries, and are made of similar materials. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.