Extremity Medical, LLC.
Brian Smekal
VP, Regulatory Affairs and Quality Assurance
300 Interpace Parkway, Suite 410
PARSIPPANY, NJ 07054

March 04, 2020

Re: K191525
Trade/Device Name: KinematX Total Wrist Arthroplasty System
Regulation Number: 21 CFR 888.3800
Regulation Name: Wrist joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWJ
Dated: January 31, 2020
Received: January 31, 2020

Dear Brian Smekal:

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,

Michael C. Owens
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)*
K191525

Device Name
KinematX Total Wrist Arthroplasty System

Indications for Use *(Describe)*
The KinematX Total Wrist Arthroplasty System is indicated for the replacement of wrist joints disabled by pain, deformity, and/or limited motion caused by:

1. Non-inflammatory degenerative wrist disease of the radiocarpal joint including osteoarthritis, post-traumatic arthritis, and Kienbock's disease
2. Revision where other devices or treatments have failed
3. Scapholunate Advanced Collapse (SLAC)
4. Rheumatoid Arthritis

The device is intended to be implanted with bone cement.

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 of Safety and Effectiveness:

KinematX Total Wrist Arthroplasty System

Submitter	Extremity Medical, LLC. 300 Interpace Parkway, Suite 410 Parsippany, NJ 07054
Contact Person	Brian Smekal, MS, RAC VP, Regulatory Affairs and Quality Assurance Phone: (973) 588-8988 Email: bsmekal@extremitymedical.com
Date Prepared	March 4, 2020
Trade Name	KinematX Total Wrist Arthroplasty System
Classification Name and Number	21 CFR 888.3800: Wrist joint metal/polymer semi-constrained cemented prosthesis
Product Code	JWJ
Common Name	Total Wrist Replacement Device
Predicate Devices	K042032, Maestro Total Wrist, Biomet, Inc. K132250, Freedom Wrist Arthroplasty System, Integra Life Sciences Corporation K021859, Remotion Total Wrist, Stryker
Device Description	The KinematX Total Wrist Arthroplasty System is a semi-constrained implant system designed to replace the joints of the wrist to alleviate pain while restoring functionality and mobility of the wrist joints. The system consists of two main, modular components: 1) Radial Implant Assembly: CoCr radial stem and an ultra-high molecular weight polyethylene (UHMWPE) bearing surface that interlocks onto a CoCr tray 2) Carpal Implant Assembly: Baseplate with central peg, index metacarpal screw, hamate screw, and CoCr cap.
Indications for use	The KinematX Total Wrist Arthroplasty System is indicated for the replacement of wrist joints disabled by pain, deformity, and/or limited motion caused by: 1) Non-inflammatory degenerative wrist disease of the radiocarpal joint including osteoarthritis, post-traumatic arthritis, and Kienbock's disease 2) Revision where other devices or treatments have failed 3) Scapholunate Advanced Collapse (SLAC) 4) Rheumatoid Arthritis The device is intended to be implanted with bone cement.

Statement of Technological Comparison	The KinematX Total Wrist Arthroplasty System is equivalent to predicate device Biomet Maestro in terms of indications for use, material design (i.e, distal metal and proximal polyethylene articulating surfaces), and material mechanical properties. The KinematX Total Wrist Arthroplasty is equivalent to the predicate device Integra Freedom in indications for use, materials and range of motion. The modular design of the KinematX tapers is equivalent to the predicate Maestro.
Non-clinical Testing	Specific testing performed on the KinematX device include: • Axial Compression Test • Construct Moment Bend Fatigue Test • Taper Disassembly Testing • Constraint Testing • Assembly Torsion Testing • Screw mechanical testing evaluation • Cadaveric evaluation • Pyrogenicity testing
Clinical Testing	No clinical testing was performed.
Conclusion	The KinematX Total Wrist Arthroplasty System is substantially equivalent to its predicate device. This conclusion is based upon indications for use, principles of operation, design, and mechanical test data.