June 2, 2022

Mako Surgical Corp.
Emily DiMambro
Staff RA Specialist
3365 Enterprise Ave
Weston, Florida 33331

Re: K220930
Trade/Device Name: Restoris Multi-Compartmental Knee System
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee Joint Femorotibial Metal/Polymer Non-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Codes: HSX, KRR, NPJ, HRY
Dated: March 31, 2022
Received: March 31, 2022

Dear Emily DiMambro:

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,

Ting Song, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K220930

Device Name

Restoris Multi-Compartmental Knee System

Indications for Use *(Describe)*

RESTORIS™ Multicompartmental Knee (MCK) System is indicated for single or multi-compartmental knee replacement used in conjunction with RIO®, the Robotic Arm Interactive Orthopedic System, in individuals with osteoarthritis or post-traumatic arthritis of the tibiofemoral and/or patellofemoral articular surfaces. The specific knee replacement configurations include:

- Medial unicondylar
- Lateral unicondylar
- Patellofemoral
- Medial bi-compartmental (medial unicondylar and patellofemoral)

RESTORIS™ Multicompartmental Knee (MCK) System is for single use only and is intended for implantation 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Manufacturer Identification

MAKO Surgical Corp.
3365 Enterprise Ave.
Weston, FL
33331 USA

Official Contact Person:

Emily DiMambro
Staff Regulatory Affairs Specialist
emily.dimambro@stryker.com
201-831-5140

Device Identification

Proprietary Name
Restoris Multicompartmental Knee System

Predicate Device
Restoris Multicompartmental Knee System - K180612

Regulatory Class
Class II

CFR Reference, Product Code, and Classification Name
21 CFR 888.3520 - HSX – Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
21 CFR 888.3540 – KRR - Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis
21 CFR 888.3560 - NPJ - Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
21 CFR 888.3530 - HRY - Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis

Device Description:
The purpose of this Changes Being Effected premarket notification is to add a contraindication for the Restoris Multicompartmental Knee (MCK) System. Additionally, minor modifications are being made to the contraindications for clarity. There is no change to the intended use, indications, design, technological characteristics or operational principles for the devices. The subject implant components are identical to the predicate components. The Restoris MCK system was most recently cleared in K180612, and has also been cleared previously in K172326, K150307, K090763, K082172, K082088, K082081, and K080368.

Intended Use:
The intended use of the subject devices is identical to the intended use described in K180612. The Restoris Multicompartmental Knee (MCK) System is indicated for single or multi-compartmental knee replacement used in conjunction with RIO®, the Robotic Arm Interactive Orthopedic System

Indications for Use:
The indications for use for the subject devices are identical to the indications for use as submitted in K180612.

RESTORIS™ Multicompartmental Knee (MCK) System is indicated for single or multi-compartmental knee replacement used in conjunction with RIO®, the Robotic Arm Interactive Orthopedic System, in individuals with osteoarthritis or post- traumatic arthritis of the tibiofemoral and/or patellofemoral articular surfaces. The specific knee replacement configurations include:

- Medial unicondylar
- Lateral unicondylar
- Patellofemoral
- Medial bi-compartmental (medial unicondylar and patellofemoral)

RESTORIS™ Multicompartmental Knee (MCK) System is for single use only and is intended for implantation with bone cement.

Summary of Technological Characteristics:
There is no change to the technological characteristics of the Restoris MCK Implant System as described in K180612. The changes described in this Changes Being Effected premarket notification do not impact the technological characteristics of the subject devices.

Non-Clinical or Clinical Testing:
No additional testing was performed as part of this submission, as the only changes being made are to the labeling for the devices. There is no impact to the device design or the physical characteristics of the devices. Testing submitted as part of previously cleared premarket notifications is applicable to this submission.

Conclusion:
The subject Restoris MCK Implant System is substantially equivalent to the predicate Restoris MCK Implant System as cleared in K180612. The subject devices are identical in intended use, indications, design, technological characteristics and operational principles as described in K180612. The only changes made to the subject devices are the additional contraindication and minor labeling clarifications.