November 6, 2024

Medisurge, LLC
Megan Morrissey
Director of QA/RA
2140 Oak Industrial Dr. NE
Grand Rapids, Michigan 49505

Re: K242412
Trade/Device Name: Agility Symmetric™ Total Knee System
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Codes: MBH, JWH
Dated: August 12, 2024
Received: August 14, 2024

Dear Megan Morrissey:

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.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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 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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2024.11.06 15:22:17 -05'00'

For Lixin Liu
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242412

Device Name

Agility Symmetric™ Total Knee System

Indications for Use *(Describe)*

Indications:
Indications for Total Knee Replacement:
1. Rheumatoid arthritis,
2. Correction of functional deformity,
3. Osteoarthritis,
4. Degenerative arthritis in older patients whose age, weight and activity level are compatible with an adequate long-term result,
5. Failed osteotomies, unicompartmental replacement, or total knee replacement.

The femoral component and tibial tray are for cemented use or uncemented use (biological fixation).

The patellar component and metaphyseal stem (K080199) are for cemented use only.

Indications for Posterior Stabilized Knee Replacement:
Posterior stabilized knee system and systems with a deep articular surface are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact. Total Knee indications still apply.

Indications for Constrained Knee Replacement:
Constrained knee systems are designed for use in patients in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/ or lateral collateral ligament) are absent or incompetent. Total Knee indications still apply.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) #: K242412

510(k) Summary

Prepared on: 2024-10-29

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Medisurge, LLC
Applicant Address	2140 Oak Industrial Dr. NE Grand Rapids MI 49505 United States
Applicant Contact Telephone	616-295-7190
Applicant Contact	Megan Morrissey
Applicant Contact Email	mmorrissey@medisurge.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Agility Symmetric™ Total Knee System
Common Name	Total Knee System
Classification Name	Prosthesis, Knee, Patello/Femorotibial, Semi-Constrained, Uncemented, Porous, Coated, Polymer/Metal/Polymer
Regulation Number	888.3565
Product Code(s)	MBH, JWH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K080199	Symmetric™ Total Knee System	JWH
K141635	Arthrex iBalance® TKA System	MBH

Device Description Summary

21 CFR 807.92(a)(4)

The Agility Symmetric™ Total Knee System is intended for the resurfacing of the knee joint. The system consists of metallic femoral and tibial components (including an available metaphyseal stem previously cleared in K080199) and a polyethylene tibial and patellar component (also cleared in K080199).

The FEMORAL COMPONENT is designed for left/right orientations. The femoral component is manufactured from cast cobalt chromium/ molybdenum (CoCrMo). The femoral component is available in five sizes (3-7) and will have two condylar pegs to aid in rotational stability. It is mesh coated with ASTM F67 titanium.

The TIBIAL TRAY is a symmetric designed component, eliminating the need for left/right orientations. The tibial component is manufactured from wrought titanium alloy (Ti6Al4V). The tibial tray features a central post, a pair of gussets, and 2 to 4 pegs on the underside providing rotational stabilization and increased tray strength. Four screw holes in the tibial tray allow for optional screw fixation. The tibial tray is designed with locking features permitting an ultra-high molecular weight polyethylene (UHMWPE) tibial insert to be snapped into place. The tibial tray has 5 sizes (3-7) and is mesh coated with ASTM F67 titanium.

Mating geometries for the previously cleared (K080199) TIBIAL INSERT, METAPHYSEAL STEM, REVISION STEM, and PATELLAR COMPONENT have not changed from the predicate devices.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Indications:
Indications for Total Knee Replacement:
1. Rheumatoid arthritis,
2. Correction of functional deformity,
3. Osteoarthritis,
4. Degenerative arthritis in older patients whose age, weight and activity level are compatible with an adequate long-term result,
5. Failed osteotomies, unicompartmental replacement, or total knee replacement.

The femoral component and tibial tray are for cemented use or uncemented use (biological fixation).

The patellar component and metaphyseal stem (K080199) are for cemented use only.

Indications for Posterior Stabilized Knee Replacement:
Posterior stabilized knee system and systems with a deep articular surface are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact. Total Knee indications still apply.

Indications for Constrained Knee Replacement:
Constrained knee systems are designed for use in patients in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligament) are absent or incompetent. Total Knee indications still apply.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications are similar between the primary predicate device and the subject device, with the exception that the primary predicate device is for cemented use only and the subject device is for cemented or uncemented use. However, the secondary predicate device is indicated for cemented or uncemented use.

Technological Comparison 21 CFR 807.92(a)(6)

The articulating geometry of the femoral components are equivalent between the primary predicate device and the subject device. The difference is that the primary predicate device is plasma sprayed with ASTM F1580 Commercially Pure Titanium and the subject device is mesh coated with ASTM F67 Commercially Pure Titanium. The changes from the primary predicate device involve the bone interface, the removal of the central post and gussets, and addition of the condylar pegs. However, the secondary predicate device is mesh coated with ASTM F67.

The geometry of the tibial tray components are equivalent. The difference is that the primary predicate device is plasma sprayed with ASTM F1580 Commercially Pure Titanium and the subject device is mesh coated with ASTM F67 Commercially Pure Titanium.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-clinical testing was conducted on the Agility Symmetric™ Total Knee System according to special controls guidance document "Knee Joint Patellofemorotibial and Femorotibial Metal Polymer Porous-Coated Uncemented Prosthesis - Class II Special Controls Guidance Document for Industry and FDA".
• The femoral knee underwent fatigue testing per ASTM F3210 to confirm the implant endurance.
• The tibial tray underwent fatigue testing per ASTM F1800 to confirm the implant endurance.
• The tibial tray and modular stem underwent fatigue testing per ASTM F1800 to confirm the combined implant endurance.
• The system underwent wear testing per ISO 14243-1, particle characterization per ASTM F1877-16.
• The system tibial locking mechanism underwent shear-off testing per ASTM 1814.
• The system underwent cleaning validation per ISO 19227.
• The system biocompatibility was assessed per ISO 10993-1.
• The system sterilization was assessed per ISO 11135 and AAMI TIR28.
• The femoral knee uncemented design was validated per ISO 21536 to confirm surgical technique guidance.
• Morse taper modular connection was assessed per ISO 21536 and ASTM F1814.
• Constraint and contact area was assessed per ASTM F1223 and ISO 21536.

Clinical Testing Not Applicable.

The proposed device has the same intended use and the predicate(s). The proposed device has similar technological characteristics to the predicate(s), and the information provided herein demonstrates that:
- any differences do not raise new questions of safety and effectiveness; and
- the proposed device is at least as safe and effective as the legally marketed predicate device(s).