July 7, 2022

MicroPort NaviBot International LLC
℅ Jinmei Zhu
Senior Manager
Shanghai MicroPort Medical (Group) Co., Ltd.
No. 1601 ZhangDong Road, ZJ Hi-Tech Park
Shanghai, Shanghai 201203
China

Re: K213873
Trade/Device Name: SkyWalker Total Knee System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: June 5, 2022
Received: June 7, 2022

Dear Jinmei Zhu:

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: Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma 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)*
K213873

Device Name
SkyWalker Total Knee System

Indications for Use *(Describe)*

SkyWalker Total Knee System is intended to assist the surgeon to perform Total Knee Arthroplasty (TKA) procedures by providing software-defined spatial boundaries for orientation and reference information to anatomical structures for the accurate placement of compatible knee implant components.

It is indicated for use in TKA procedures in which the selection of stereotactic surgery is appropriate and the anatomical bony structures can be identified with a CT based model.

SkyWalker Total Knee System includes surgical console (a robotic arm platform), navigation console (an optical tracking navigation platform), software system (including preoperative planning software), cables, surgical instruments and accessories. The robotic arm placement is performed relative to anatomical landmarks as recorded using the system intraoperatively and based on a preoperative plan derived from imported CT images.

The targeted population as well as indications and contraindications have the same characteristics as those suitable for the following implants compatible with SkyWalker Total Knee System: EVOLUTION® MP TOTAL KNEE SYSTEM, EVOLUTION® MP TOTAL KNEE SYSTEM, ADVANCE® STATURE FEMORAL COMPONENT, ADVANCE® TIBIAL COMPONENT, and ADVANCE® KNEE SYSTEM.

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.

510(k) Summary

510(k) Submitter:	MicroPort NaviBot International LLC 300 Foxborough Blvd., Foxborough MA, 02035 USA
Contact Person：	Mike Manor Manor.Michael@microport.com Phone: (508)-561-0097
Date Prepared：	December 10, 2021
Device Trade Name:	SkyWalker Total Knee System
Device Classification Name:	Stereotaxic Instrument
Regulation Number:	21 CFR 882.4560
Classification Product Code:	OLO
Device Class：	Class II

1. Substantial Equivalence Claimed To

The subject device, SkyWalker Total Knee System, is substantially equivalent to the predicate device, ROSA Knee System, cleared under K182964.

2. Indications for Use

SkyWalker Total Knee System is intended to assist the surgeon to perform Total Knee Arthroplasty (TKA) procedures by providing software-defined spatial boundaries for orientation and reference information to anatomical structures for the accurate placement of compatible knee implant components.

It is indicated for use in TKA procedures in which the selection of stereotactic surgery is appropriate and the anatomical bony structures can be identified with a CT based model.

SkyWalker Total Knee System includes surgical console (a robotic arm platform), navigation console (an optical tracking navigation platform), software system (including preoperative planning software), cables, surgical instruments and accessories. The robotic arm placement is performed relative to anatomical landmarks as recorded using the system intraoperatively and based on a preoperative plan derived from imported CT images.

The targeted population as well as indications and contraindications have the same characteristics as those suitable for the following implants compatible with SkyWalker

Total Knee System: EVOLUTION® MP TOTAL KNEE SYSTEM, EVOLUTION® MP TOTAL KNEE SYSTEM, ADVANCE® STATURE FEMORAL COMPONENT, ADVANCE® TIBIAL COMPONENT, and ADVANCE® KNEE SYSTEM.

3. Compatible Implant System

Following implant system are compatible with SkyWalker Total Knee System:

- EVOLUTION® MP TOTAL KNEE SYSTEM (K093552 and K102380)
  - Femoral components:
    Size 1, Size 2, Size 3, Size 4, Size 5, Size 6, Size 7 and Size 8
  - Tibial components:
    Size 1, Size 2, Size 3, Size 4, Size 5, Size 6, Size 7, Size 8, Size 2+, Size 6+ and Size 8+
- ADVANCE® STATURE FEMORAL COMPONENT (K063731)
  - Size 2-STATURE, Size 3-STATURE and Size 4-STATURE
- ADVANCE® TIBIAL COMPONENT (K960617)
  - Size 1, Size 2, Size 3, Size 4, Size 5, Size 6, Size 1+, Size 2+, Size 3+, Size 4+ and Size 5+
- ADVANCE® KNEE SYSTEM (K972626)
  - Size 1, Size 2, Size 3, Size 4, Size 5, and Size 6

4. Device Description

SkyWalker Total Knee System consists of a navigation console, a surgical console, cables, software system, surgical instruments and disposables. The navigation console includes a navigation trolley, an optical tracking device, a primary monitor and a surgeon monitor. The surgical console includes a robotic arm, a robotic arm trolley and a foot pedal.

The TKA surgery workflow under the guidance of SkyWalker Total Knee System can be divided into preoperative procedure and intraoperative procedure. The preoperative procedure is to assist the user with preoperative planning by using patient CT image data and providing reference information to anatomical structures to make a surgical plan for the TKA surgery. In the intraoperative procedure, Skywalker Total Knee System can provide stereotactic guidance for real-time orientation of the cutting block to a target position with a target pose. When the robotic arm reaches the target position, the cutting block is being held in an expected pose, then the surgeon could be able to accurately perform knee resection.

5. Summary of Technological Characteristics

The rationale for substantial equivalence is based on the same principle of robotic image-guided TKA surgery as well as on consideration of the following technological characteristics:

- The subject device and the predicate device consist of major components including a robotic arm unit, an optical navigation unit, software system, surgical instruments and accessories.
- The subject device and the predicate device create 3D bone model of the patient's femur and tibia.
- The subject device and the predicate device give reference information to anatomical structures.
- The subject device and the predicate device allow for a preoperative surgical plan and provide visualization of planned cut planes.
- The subject device and the predicate device use dedicated instruments to coordinate with the optical tracking device and to acquire spatial location by real-time detecting the markers.
- The subject device and the predicate device provide intraoperative registration of the spatial position of the bony anatomy, utilize fiducial landmarks put on the patient's femur and tibia intraoperative to match the preoperative surgical plan and align the reference anatomy axis.
- The subject device and the predicate device provide software-guided spatial position and orientation of a cutting guide.
- The subject device and the predicate device assists in intraoperative navigation of a cutting guide to the patient's knee anatomy and facilitate accurate resection for compatible implant placement.
- The subject device and the predicate device provide an interactive user interface to operate the device.

The subject device differs from the predicate device in technological characteristics as follows:

- The subject device utilizes Computed Tomography (CT) image data, whereas the predicate device uses Magnetic Resonance (MR) and X-Ray image data.
- The subject device provides robot position repeatability ≤ 0.5mm, robot orientation repeatability ≤ 1.0°, navigation accuracy with mean of errors ≤ 0.5mm, and subsequently suffices for the system accuracy of cutting position accuracy ≤ 1.5mm and cutting orientation accuracy ≤ 2.0°.

6. Summary of Performance Data

The following performance data is provided in support of the substantial equivalence determination:

- **Biocompatibility Evaluation**

The biocompatibility evaluation for SkyWalker Total Knee System was conducted in accordance with ISO 10993 and FDA guidance on *Use of International Standard ISO 10993-*

1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The evaluation reveals that SkyWalker Total Knee System meets biocompatibility requirements.

- **Electrical Safety and Electromagnetic Compatibility (EMC)**

Electrical safety testing and EMC testing were conducted, demonstrating that SkyWalker Total Knee System complies with recognized electrical safety standards: *IEC 60601-1:2005+AMD1:2012 standard* for electrical safety and *IEC 60601-1-2:2014* standard for electromagnetic compatibility.

- **Device Performance Testing**

V&V tests for SkyWalker Total Knee System were conducted with the following aspects:

- Bench Performance Test, to ensure the essential performance of SkyWalker Total Knee System and verify design inputs of critical features.
- Accelerated Aging Test, to ensure the sterile Marker's package integrity and performance within its shelf life claim.
- Reprocessing Validation Test, to demonstrate the validity of cleaning method and sterilization parameters.
- Human Factor Engineering, to address user interactions with SkyWalker Total Knee System.
- Cadaveric Validation Test, to validate SkyWalker Total Knee System is safe and effective by orthopedic surgeons' simulated uses on cadaveric specimens, and provide evidence that the performances of SkyWalker Total Knee System satisfy the intended use.

- **Software Verification and Validation Testing**

Software tests were conducted to satisfy the requirements of the FDA guidance on *Content of Premarket Submissions for Software Contained in Medical Devices* and IEC 62304 *Medical Device Software- Software Life Cycle Processes*. The software contained in SkyWalker Total Knee System was considered a "major" level of concern. The testing demonstrates that SkyWalker Total Knee System does not raise any new issues of safety and effectiveness as compared to the predicate device.

7. Conclusion

The non-clinical data support the safety of SkyWalker Total Knee System, and the V&V testing provide evidence that SkyWalker Total Knee System perform as intended in the specified use conditions. Any differences between the subject device and the predicate device do not raise new questions of safety and effectiveness, hence the subject device SkyWalker Total Knee System is as safe, as effective, and performs comparably to the predicate device for the same intended use.