



Orthosoft Inc. (d/b/a Zimmer CAS)
Paul Hardy
Sr. Specialist, Regulatory Affairs
75 Queen Street Ste. 3300
Montreal QC, H3C 2N6 CA

January 24, 2019

Re: K182964
Trade/Device Name: ROSA Knee System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: October 24, 2018
Received: October 25, 2018

Dear Paul Hardy:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Jesse
Muir -S** Digitally signed
by Jesse Muir -S
Date: 2019.01.24
11:17:06 -05'00'

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K182964

Device Name

ROSA® Knee System

Indications for Use (Describe)

The ROSA® Knee System is indicated as a stereotaxic instrumentation system for total knee replacement (TKA) surgery. It is to assist the surgeon in providing software-defined spatial boundaries for orientation and reference information to identifiable anatomical structures for the accurate placement of knee implant components.

The robotic arm placement is performed relative to anatomical landmarks as recorded using the system intraoperatively, and based on a surgical plan, optionally determined pre-operatively using compatible X-ray or MRI based surgical planning tools.

It includes a robotic arm, an optical sensor navigation system and accessories, software system, surgical instruments and accessories.

The targeted population has the same characteristics as the population that is suitable for the implants compatible with the ROSA® Knee System. The ROSA® Knee System is to be used with the following fixed bearing knee replacement systems in accordance with their indications and contraindications:

NexGen® CR, NexGen CR-Flex, NexGen CR-Flex Gender, NexGen LPS, NexGen LPS-Flex, NexGen LPS-Flex Gender, Persona® CR, Persona PS, Vanguard® CR, and Vanguard PS.

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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K182964

510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the ROSA[®] Knee System 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor: Zimmer CAS d/b/a Orthosoft, Inc.
75 Queen St., Suite 3300
Montreal, QC, CANADA H3C 2N6
Establishment Registration Number: 9617840

Contact Person: Paul Hardy
Regulatory Affairs Sr. Specialist
Telephone: 574-372-6799

Date: January 23, 2019

Subject Device: **Trade Name:** ROSA[®] Knee System
Common Name: ROSA[®] Knee System

Classification Name:

- OLO– Orthopedic Stereotaxic Instrument (21 CFR 882.4560)

Predicate Device(s):

Manufacturer	Device Name	510(k) Number
Medtech S.A.	ROSA Spine	K151511
MAKO Surgical Corp.	Mako Total Knee Application	K172219

Purpose and Device Description:

The ROSA[®] Knee System is used to assist surgeons in performing Total Knee Arthroplasty (TKA) with features to assist with the bone resections as well as assessing the state of the soft tissues to facilitate implant positioning intra-operatively. The ROSA[®] Knee System uses a Medical Device Data System (MDDS) called the Zimmer

Biomet Drive Portal which manages the creation and tracking of surgical cases. The cases reside on the portal until it is uploaded to the ROSA[®] Knee System before surgeries.

If the case is image-based, a 3D virtual bone model is generated pre-operatively by the PSI systems (X-PSI Knee System or CAS PSI Knee System) to create a model of the patient's femur/tibia and allows for the preparation of a pre-operative surgical plan as well as visualization of planned cuts. The pre-operative plan is then matched to the landmarks taken intra-operatively on the patient's bony anatomy. An imageless option is also available where landmarks taken intra-operatively on the patient's bony anatomy are used to create the surgical plan directly in the surgery. Accuracy of resections, knee state evaluation, and soft tissue assessment are the same between image-based and imageless options as they are always based on intra-operative landmarks.

The intra-operative workflow and surgical concepts implemented in the system remain close to the conventional TKA workflow. As such, at the time of the surgery, the system mainly assists the surgeon in (1) determining reference alignment axes in relation to anatomical landmarks, (2) planning the orthopedic implants location based on these reference alignment axes and orthopedic implant geometry (planning optionally based on a pre-operative plan using pre-operative imaging), and (3) precisely positioning the cut guide relative to the planned orthopedic implant location by using a robotic arm.

Indications for Use:

The ROSA[®] Knee System is indicated as a stereotaxic instrumentation system for total knee replacement (TKA) surgery. It is to assist the surgeon in providing software-defined spatial boundaries for orientation and reference information to identifiable anatomical structures for the accurate placement of knee implant components.

The robotic arm placement is performed relative to anatomical landmarks as recorded using the system intraoperatively, and based on a surgical plan, optionally determined pre-operatively using compatible X-ray or MRI based surgical planning tools.

It includes a robotic arm, an optical sensor navigation system and accessories, software system, surgical instruments and accessories.

The targeted population has the same characteristics as the population that is suitable for the implants compatible with the ROSA[®] Knee System. The ROSA[®] Knee System is to be used with the following fixed bearing knee replacement systems in accordance with their indications and contraindications: NexGen[®] CR, NexGen CR-Flex, NexGen CR-Flex Gender, NexGen LPS, NexGen LPS-Flex, NexGen LPS-Flex Gender, Persona[®] CR, Persona PS, Vanguard[®] CR, and Vanguard PS.

Contraindications:

The ROSA[®] Knee System may not be suitable for use in case of:

- hip pathology with significant bone loss (e.g. avascular necrosis of the femoral head with collapse, severe dysplasia of the femoral head or the acetabulum);
- hip pathology severely limiting range of motion (e.g. arthrodesis, severe contractures, chronic severe dislocation);
- active infections of the knee joint area;
- knee replacement revision surgery;
- presence of strong infrared sources or infrared reflectors in the vicinity of the trackers;
- contraindications for the implant as given by the implant manufacturer; and
- implants that are not compatible with the system

Summary of Technological Characteristics:

The rationale for substantial equivalence is based on consideration of the following characteristics:

- The proposed and predicate device(s) are intended to assist the surgeon in providing software defined spatial boundaries for orientation
- The proposed and predicate device(s) assists in intraoperative navigation of the patient's anatomy and are utilized to facilitate implant positioning
- The propose and predicate device(s) assist in joint balancing techniques

- The proposed and predicate device(s) utilizes image data that has been segmented to create a 3D model of the patient's bony anatomy
- The proposed and predicate device(s) consists of major components including a robotic arm, software system, navigation system, various instrumentation including reusable and disposable

**Summary of Performance Data
(Nonclinical and/or Clinical)**

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

Biocompatibility Testing

The biocompatibility evaluation for ROSA Knee was conducted in accordance with ISO 10993. The evaluation reveals that the ROSA Knee device meets biocompatibility requirements.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing was conducted on ROSA Knee. The device complies with recognized electrical safety standards: IEC 60601-1 standard for electrical safety and IEC 60601-1-2 standard for electromagnetic compatibility.

Device Performance Testing

Verification and Validation Testing for ROSA Knee was conducted with the following aspects:

- Physical/Performance Tests- to ensure the performance of the implemented features and verify related design inputs
- Engineering Analysis- to ensure the performance of the implemented features and verify related design inputs
- Usability Engineering- addressed user interactions with the ROSA Knee
- Validation Lab- performed to validate that using the ROSA Knee is safe and effective and that the performances of the ROSA Knee are acceptable under full simulated use on cadaveric specimens

Software Verification and Validation Testing

Software tests were conducted to satisfy the requirements of the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices and IEC 62304 (Medical Device Software- Life Cycle Process). The software was considered a “major” level of concern, since a failure of the software could result in serious injury or death to the patient. The testing demonstrates that the ROSA Knee does not raise any new issues of safety and effectiveness as compared to the predicate device(s).

Substantial Equivalence Conclusion

The proposed and predicate device(s) have the same intended use and similar technological characteristics with the exception that the proposed device utilizes Magnetic Resonance (MR) and X-Ray image data and the predicate device(s) uses Computed Tomography (CT). These imaging modalities have been used in various Zimmer Biomet platforms. In addition, the proposed device uses cutting blocks to assist with bone preparation similar to traditional manual total knee arthroplasty while the predicate device(s) are equipped with an automated cutting system that does not require cutting blocks or pedicle screws that are placed by the surgeon and surgical tools are inserted in tool guides on the robotic arm. In sum, any differences between the devices 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).