OMNIlife Science Inc.
Christina Rovaldi
Regulatory Affairs Specialist
480 Paramount Drive
Raynham, Massachusetts 02767

Re: K163338
Trade/Device Name: OMNIBotics® Knee System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: August 18, 2017
Received: August 21, 2017

Dear Christina Rovaldi:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Katherine D. Kavlock -S

for
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)
K163338

Device Name
OMNiBotics® Knee System

Indications for Use (Describe)

The OMNiBotics® Knee System is indicated for stereotaxic surgery to aid the surgeon in locating anatomical structures and aligning endoprosthesis with these anatomical structures during Total Knee Arthroplasty. The Active Spacer is indicated as a tool for adjustment of soft tissue and the femoral implant to reduce instability from flexion gap asymmetry. The OMNiBotics® Knee System supports OMNI Apex Knee™ System implants.

Type of Use (Select one or both, as applicable)

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

*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:

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510(k) Summary

Submitter: OMNIlife Science Inc.
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Fax number: 508-822-6030
FDA Registration #: 1226188

Contact person: Christina Rovaldi, Regulatory Affairs Specialist
Phone number: 1-774-226-1857
Fax number: 508-822-6030

Date prepared: July 27, 2017

Trade name: OMNIBotics® Knee System
Classification Name: Orthopedic Stereotaxic Instrument
Product Code: OLO
Regulation: 21 CFR 882.4560

Substantial equivalence claimed to:
K090953: TOTAL KNEE SURGETICS Navigation System with IBlock® (Primary Predicate)
K150372: VERASENSE Knee System
K132104: eLibra® Soft Tissue Force Sensor

Description:
The OMNIBotics® Knee system is a computer-assisted navigation system with a motorized bone cutting guide that is used by surgeons and OR staff to assist in performing stereotaxic total knee arthroplasty (TKA). The OMNIBotics® Knee System consists of the OMNIBotics® Station, ART Knee Application software, the iBlock® cutting guide for guiding femoral bone resections, and the Active Spacer, an active (motorized) knee spacer and ligament tensioning device for knee ligament balancing.

The OMNIBotics® Station includes a 3D optoelectronic localizer mounted on an articulated arm, a laptop hosting the ART Knee Software and equipped with a touchscreen, an external LCD monitor and a three-button footswitch as a means for the user to interact with the system. The power supply and communication hardware required for the camera, the laptop, the iBlock® and the Active Spacer are contained within a single enclosure, the control box, located at the base of the Station.

Indications for Use:
The OMNIBotics® Knee System is indicated for stereotaxic surgery to aid the surgeon in locating anatomical structures and aligning endoprostheses with these anatomical structures during Total K163338
1 of 4
Knee Arthroplasty. The Active Spacer is indicated as a tool for adjustment of soft tissue and the femoral implant to reduce instability from flexion gap asymmetry. The OMNIBotics® Knee System supports OMNI Apex Knee™ System implants.

**Technological Characteristics**

The underlying technology of the OMNIBotics® Knee System is the same as the predicate device TOTAL KNEE SURGETICS Navigation System with iBlock® K090953. The system is based on the same operating principle and control, mechanism to provide the user with the same kind of information and guidance for the same surgery. The main changes with respect to the predicate device concern the modification of the ART software suite for navigation, and the addition of the Active Spacers for tensioning balance of the knee.

**Technological Characteristics Compared to Predicate Device:**

<table>
<thead>
<tr>
<th>General Characteristic</th>
<th>OMNIBotics® Knee System</th>
<th>TOTAL KNEE SURGETICS Navigation System with iBlock® (K090953)</th>
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</thead>
<tbody>
<tr>
<td>Indications for Use</td>
<td>The OMNIBotics® Knee System is indicated for stereotaxic surgery to aid the surgeon in locating anatomical structures and aligning endoprostheses with these anatomical structures during Total Knee Arthroplasty. The Active Spacer is indicated as a tool for adjustment of soft tissue and the femoral implant to reduce instability from flexion gap asymmetry. The OMNIBotics® Knee System supports OMNI Apex Knee™ System implants.</td>
<td>The Total Knee Surgetics Navigation System with iBlock® is intended for use stereotaxic surgery to aid the surgeon in locating anatomical structures and aligning the endoprostheses with the anatomical structures. It is specifically indicated for: Total Knee Arthroplasty</td>
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</tbody>
</table>
| Station                | - A 3D optical localizer (OTS camera)  
- A Microsoft Windows based laptop computer that runs application specific (ART knee) software  
- One electronics enclosure containing power supplies and communication hardware for the iBlock®, optical camera, and active spacer  
- 31.5 inch display monitor  
- A mobile OTS cart | - A 3D optical localizer (OTS camera)  
- A Microsoft Windows based panel computer that runs application specific (TKS knee) software  
- Two electronics enclosures containing power supplies and communication hardware for the iBlock®, and optical camera  
- 17 inch display monitor  
- A mobile custom designed cart |
<table>
<thead>
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<th>TOTAL KNEE SURGETICS Navigation System with iBlock® (K090953)</th>
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<tr>
<td>ART Software:</td>
<td>Total knee navigation software based on imageless (CT-free) registration of the knee morphology and leg mechanical axis</td>
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<td>- Measured resection and ligament balancing profiles</td>
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<td>- Tibiofemoral gap measurements throughout flexion</td>
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<td>- Flexible workflows though the use of an onscreen menu</td>
<td>- Linear workflows pre-established in user profile preferences</td>
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<td>- GUI formatted for 16:9 display ratio</td>
<td>- GUI formatted for 5:4 display ratio</td>
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<tr>
<td>Instruments:</td>
<td>Rigid bodies equipped with sterile single-use markers</td>
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<td></td>
<td>- Adjustable cutting guide for tibial cut and/or distal femoral cut</td>
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<tr>
<td>iBlock® motorized</td>
<td>Universal motorized cutting guide for positioning a saw-guide to the five femoral component resections</td>
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<td>cutting guide</td>
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In addition to the comparison of the core functionality of the OMNIBotics® Knee System to the TOTAL KNEE SURGETICS Navigation System with iBlock®, new features are provided with the OMNIBotics® Knee System through the use of the Active Spacer. The Active Spacer includes two independently controlled actuators for distraction and two force sensors for sensing loads on the medial and lateral compartments of the knee. The actuators are controlled in position control (to apply a controlled height) and in force control (to apply a controlled force, in Newtons), equivalent to the VERASENSE Knee System (K150372) and the eLibra® Soft Tissue Force Sensor (K132104) respectively.

In summary, the OMNIBotics® Knee System with the Active Spacer is substantially equivalent to the TKS Navigation System when combined with the Versasense and the eLibra® devices in device functionality and intended use, and safety and effectiveness is supported by the testing performed.

**Verification and Validation Documentation**

The OMNIBotics® Knee System tests include cadaver testing and verification and validation performance testing to demonstrate no new safety and efficacy issues are raised with this new device. Analyses demonstrate that system accuracy and performance are adequate for the established intended use. In conclusion, the modified OMNIBotics® Knee System is substantially equivalent to the predicate devices.
Conclusion:
This performance of the OMNIBotics® Knee System is substantially equivalent to that of the TOTAL KNEE SURGETICS Navigation System with iBlock® (K090953) combined with the Versasense position control and the eLibra® force control. The OMNIBotics® Knee System has been demonstrated to be substantially equivalent to the predicate devices and raises no new concerns related to safety or efficacy.