January 14, 2021

DePuy Ireland UC
Stéphanie Elvin
Regulatory Affairs Manager
Loughbeg, Ringaskiddy
Ireland

Re: K202769
Trade/Device Name: VELYS™ Robotic-Assisted Solution
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: December 18, 2020
Received: December 22, 2020

Dear Stephanie Elvin:

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K202769

Device Name
VELYS™ Robotic-Assisted Solution

Indications for Use *(Describe)*

The VELYS™ Robotic-Assisted Solution is intended for stereotaxic surgery to aid the surgeon in identifying the relative position and orientation of anatomical structures, planning the position of the femoral and tibial implant components intraoperatively, and preparing the bones during total knee arthroplasty.

The VELYS™ Robotic-Assisted Solution is indicated for use with the ATTUNE Total Knee System and its cleared indications for use.

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.

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510(k) SUMMARY
(As required by 21 CFR 807.92)

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg, Ringaskiddy Co. Cork Munster, IRELAND
Phone number	574-372-7211
Fax number	574- 371-4987
Establishment Registration Number	3015516266
Name of contact person	Stéphanie Elvin selvin@jnj.its.com, Karen Mahoney kmahoney@its.jnj.com
Date prepared	18 December 2020
Name of device	
Trade or proprietary name	VELYS™ Robotic-Assisted Solution
Common or usual name	Surgical Navigation System
Classification name	Orthopedic Stereotaxic Instrument
Class	II
Classification panel	87 Orthopedics
Regulation	882.4560
Product Code(s)	OLO
Legally marketed device(s) to which equivalence is claimed	TOTAL KNEE SURGETICS Navigation System with iBlock (K090953)
Reason for 510(k) submission	New Device
Device description	The VELYS™ Robotic-Assisted Solution is an image-free robotic-assisted surgery system for Total Knee Arthroplasty (TKA). It is intended for stereotaxic surgery to aid the surgeon in identifying the relative position and orientation of anatomical structures and landmarks, planning the position of the femoral and tibial implant components intraoperatively, and preparing the bones during total knee arthroplasty. The image-free system uses a dedicated optical tracking device to acquire anatomical landmarks intra-operatively. These landmarks are then used to plan the femoral and tibial implant locations based on the surgeon's preferred surgical technique and placement preferences. Following the planning step, the VELYS™ Robotic-Assisted Solution helps the surgeon to execute the bone preparation according to the plan.

	The system includes a Robotic-Assisted Device that constrains the position and orientation of the saw handpiece and blade inside each plane corresponding to each resection on the patient's femur and tibia. The surgeon actuates and manipulates the saw handpiece, within the planned resection plane, to execute the bone resection. This is analogous to using manual instruments in TKA and the way the surgeon uses the saw handpiece in the predicate device. If the patient's leg moves during the resection, the Robotic-Assisted Device compensates for such movement in real-time. The Robotic-Assisted Device is assembled with a Robotic-Assisted Device arm, mounted on the Operating Room (OR) bed rail, for a minimal footprint. The VELYS™ Robotic-Assisted Solution incorporates several software sub-systems, including applications responsible for general operation of the system and a Clinical Application dedicated to the surgery workflow. The users interact with the Clinical Application via a touchscreen and footswitch to navigate through the surgery steps. Case Reports including key surgical procedure information are stored on the system and can be retrieved by the surgeon for future use.
Indications for use	The VELYS™ Robotic-Assisted Solution is intended for stereotaxic surgery to aid the surgeon in identifying the relative position and orientation of anatomical structures, planning the position of the femoral and tibial implant components intraoperatively, and preparing the bones during total knee arthroplasty. The VELYS™ Robotic-Assisted Solution is indicated for use with the ATTUNE Total Knee System and its cleared indications for use.

Summary of the Technological Characteristics of the Device Compared to the Predicate Device		
Characteristics	**Subject Device:** **VELYS™ Robotic-Assisted Solution** **DePuy Ireland UC**	**Predicate Device:** **Total Knee Surgetics Navigation System with iBlock, OMNILife Science Inc.** **K090953 Cleared Jan 21, 2010**
Indications for Use	The VELYS™ Robotic-Assisted Solution is intended for stereotaxic surgery to aid the surgeon in identifying the relative position and orientation of anatomical structures, planning the position of the femoral and tibial implant components intraoperatively, and preparing the bones during total knee arthroplasty. The VELYS™ Robotic-Assisted Solution is indicated for use with the ATTUNE™ Total Knee System and its cleared indications for use.	The Total Knee Surgetics Navigation System with iBlock is intended for use during stereotaxic surgery to aid the surgeon in locating anatomical structures and aligning endoprostheses with the anatomical structures. The Total Knee Surgetics Navigation System with iBlock is specifically indicated for Total Knee Arthroplasty
Principles of operation	• Uses established computer-assisted orthopaedic surgery technologies to prepare the bone • Optical localization technology is used to collect intraoperative data and track relative position of the bones and instruments during surgery • A motorized instrument controlled by the system automatically positions the resection plane (saw blade) within the planned plane for the bone resection and maintains alignment through dynamic compensation. • Image-free technology	• Uses established computer-assisted orthopaedic surgery technologies to prepare the bone • Optical localization technology is used to collect intraoperative data and track relative position of the bones and instruments during surgery • A motorized instrument controlled by the system automatically positions the resection plane (cutting guide) to the planned plane for the bone resection. • Image-free technology
Stations	• Base station: camera, power supply, Robot Control Unit, display monitor, foot pedal • Satellite station: optional touchscreen, storage for Robotic-Assisted Device and Robotic-Assisted Device arm, transfer mechanism to assist with transfer to bedrail	• One station: camera, power supply unit, control box for robot, computer unit, display monitor, foot pedal
Software	• Dedicated TKA application software	• Dedicated TKA application software

Discussion of Similarities and Differences Between the Device and the Predicate Device
The VELYS™ Robotic-Assisted Solution (Subject device) and the TOTAL KNEE SURGETICS Navigation System with iBlock (Predicate device) have the same intended use and are both indicated for TKA surgery. Both devices are image-free and use Stereotaxic / Computer Assisted Surgery (CAS) technology to localize bone structures and track their position relative to the instruments during surgery. The systems use very similar setups with one or two stations holding a camera, computer units, power supply, and display monitors; dedicated instruments sets, containing in arrays with reflective markers; and instruments such as drill pins and clamps for attaching arrays to the bones. The VELYS™ Robotic-Assisted Solution includes a dedicated cabled Saw Handpiece. Operation of the systems is very similar; the surgeon registers bone anatomy using a pointer, the system software provides a visual bone model and allows the surgeon to plan resections. Based on the surgical plan, the system positions either a cutting guide (in the predicate) or the Saw Handpiece (for the subject device) in the correct position to allow the surgeon to execute the planned resection. The surgical flows are very similar, and the surgeon can choose the order of cuts to perform via the Graphic User Interface (GUI). Surgical techniques provided with the proposed and predicate devices are specific to the implants they are indicated for use with. The devices differ slightly in the way they provide a resection plane. In the predicate device, a cutting guide is positioned by a motorized instrument and the surgeon places the sawblade through the slot in the guide to perform the resection. In the subject device, a motorized instrument holds the Saw Handpiece in the correct plane for the surgeon to execute the primary resections; there is no physical cutting guide, the cutting guide is effectively virtualized. Software in the subject device establishes the desired resection plane, tracks the positioning of Arrays in real-time and adjusts the position of the Saw Blade to compensate for any movement of the patient leg. In the predicate device, the cutting guide is mounted on the patient's femur to ensure the cutting guide position is maintained relative to the bone.
Performance Data
Summary of Non-Clinical Tests Conducted for Determination of Substantial Equivalence
Design verification tests were performed on the VELYS™ Robotic-Assisted Solution in accordance with the product risk analysis and product requirements and to demonstrate substantial equivalence to the predicate device. Testing performed for assessing device performance include Performance Testing, Electrical Safety, Electromagnetic Compatibility, Biocompatibility, Sterilization, Packaging, Transport, Software and Usability. Simulated use testing included testing on simulated knees (sawbones) and cadavers. Users included surgeons and Operating Room staff, who were able to successfully use the VELYS™ Robotic-Assisted Solution to implant ATTUNE Total Knee System per specification.

Testing was performed that demonstrated compliance to the following standards:

AAMI ANSI ISO 11137-1:2006 (R) 2015 Sterilization of healthcare products - Radiation Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

ISO 11137-2:2013 Sterilization of health care products - Radiation Part 2: Establishing the sterilization dose

ISO 11607-1:2019 Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems

ISO 11607-2:2019 Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for Forming, Sealing and Assembly Processes.

ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

IEC 60601-1:2005 + A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

AAMI ES60601-1:2005 and A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2014 Medical electrical equipment - Part 2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

IEC 80601-2-77:2019 Particular requirements for the BASIC SAFETY and essential performance of ROBOTICALLY ASSISTED SURGICAL EQUIPMENT

ASTM F2554-18 Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems

ASTM F3107-14 Standard Test Method for Measuring Accuracy after Mechanical Disturbances on Reference Frames of Computer Assisted Surgery Systems

Subject and predicate devices were tested to the same international standards for key requirements such as Electrical Safety and EMC, as well as Biocompatibility, supporting substantial equivalence.

In addition to standard-driven testing, the following test was performed to compare the system navigation accuracy and support substantial equivalence to the predicate:

- Accuracy and repeatability study, which concluded the system localization accuracy of the subject is the same as the predicate.

The following tests were performed to support Safety and Efficacy of the proposed device as they pertain to features specific to the proposed device:

- Dynamic-compensation performance test.
- Accuracy test bench study to confirm the accuracy of the saw blade position.
- Boundary Limit Essential Performance test.
- Cadaveric Accuracy study to confirm resection accuracy compared to conventional instruments.
- Design Validation study.

Non-Clinical testing supports Substantial Equivalence of the subject device VELYS™ Robotic-Assisted Solution to the predicate device TOTAL KNEE SURGETICS Navigation System with iBlock

Summary of Clinical Tests Conducted for Determination of Substantial Equivalence and/or of Clinical Information

No clinical tests were conducted to demonstrate substantial equivalence.

Conclusions Drawn from Non-Clinical and Clinical Data

The subject VELYS™ Robotic-Assisted Solution is substantially equivalent to the predicate TOTAL KNEE SURGETICS Navigation System with iBlock.