December 14, 2023

DePuy Ireland UC
Bastien Michel D'annoville
Senior Regulatory Affairs Specialist
Loughbeg
Ringaskiddy, Co. Cork Munster
Ireland

Re: K233227
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: September 29, 2023
Received: November 16, 2023

Dear Bastien Michel D'annoville:

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.

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,

Tejen D. Soni -S

For
Shumaya Ali, MPH
Assistant Director

DHT6C: Stereotaxic, Bone Growth Stimulators, and Fracture Fixation 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.

Submission Number *(if known)*

K233227

Device Name

VELYS™ Robotic-Assisted Solution

Indications for Use *(Describe)*

The VELYS™ Robotic-Assisted Solution is intended for stereotaxic surgery to help the surgeon to identify the relative position and orientation of anatomical structures, plan the position of the femoral and tibial implant components intraoperatively and prepare 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.

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510(k) #: K233227

510(k) Summary

Prepared on: 2023-11-16

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	DePuy Ireland UC
Applicant Address	Loughbeg Ringaskiddy Ireland
Applicant Contact Telephone	+33(0)679888395
Applicant Contact	Mr. Bastien Michel d'Annoville
Applicant Contact Email	bdannovi@its.jnj.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	VELYS™ Robotic-Assisted Solution
Common Name	Stereotaxic instrument
Classification Name	Orthopedic Stereotaxic Instrument
Regulation Number	882.4560
Product Code	OLO

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K202769	VELYS™ Robotic-Assisted Solution	OLO

Device Description Summary

21 CFR 807.92(a)(4)

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. 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 subsystems, 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. Cases Reports

including PHI are only available to the surgeon who performed the procedure.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The VELYS™ Robotic-Assisted Solution is intended for stereotaxic surgery to help the surgeon to identify the relative position and orientation of anatomical structures, plan the position of the femoral and tibial implant components intraoperatively and prepare 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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The proposed device has the same indications for use as the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The subject device and predicate device have the same intended use, classification and principles of operation.

The subject device and predicate device have the same Surgical Workflow, including preoperative setup steps, anatomical registration, joint balance assessment, implant positioning planning and bone resection. They also have the same technological characteristics, and the same patient contact materials and energy source.

The subject device shows some differences regarding the network connectivity during non-clinical use.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The following tests were performed on the VELYS Robotic-Assisted Solution to demonstrate substantial equivalence of safety and efficacy with the predicate device:
- Functional System Integration Test
- Full software verification test campaign, including unit, integration, and software systeml-evel testing
- Cybersecurity testing, including penetration testing

No clinical tests were conducted to demonstrate substantial equivalence.