June 25, 2026

Depuy Ireland UC
Taylen Curenton
Sr Regulatory Affairs Specialist
Loughbeg
Ringaskiddy,
Ireland

Re: K260480
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: March 26, 2026
Received: March 27, 2026

Dear Taylen Curenton:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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, 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260480

Please provide the device trade name(s).

VELYS™ Robotic-Assisted Solution

Please provide your Indications for Use below.

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.

When indicated for total knee arthroplasty, the VELYS™ Robotic-Assisted Solution is indicated for use with the ATTUNE™ Total Knee System and its cleared indications for use.

Please select the types of uses (select one or both, as applicable).

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

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [ ] Adolescents (12 years old to < 22 years old)
- [ ] Adults (22 years old and greater)

510(k) #: K260480

510(k) Summary

Prepared on: 2026-06-22

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	DePuy Ireland UC
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Correspondent Contact	Taylen Curenton
Correspondent Contact Email	tcurento@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(s)	OLO

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K233227	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. 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 (TKA) and unicompartmental knee arthroplasty (UKA).

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

resection plane 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 or UKA. 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 clinical applications dedicated to the surgery workflow.

The users interact with the clinical applications 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. Case 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 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.

When indicated for 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 subject 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 technological characteristics in regards to principles of operation, system design, and energy source. The subject device and predicate device have the same overall surgical workflow, including preoperative setup steps, anatomical registration, joint balance assessment, implant positioning planning and bone resection, and the same patient contact materials and intended use.

The technological characteristics that differ in the subject device consist of updates that include an optional planning functionality to create a custom surgical plan based on surgeon planning preferences, enhancements to existing acquisition functionality, and general updates to the current workflow steps.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Bench testing was performed on the subject device: VELYS™ Robotic-Assisted Solution including Total Knee Arthroplasty (TKA) system software version 2.0.1. The VELYS™ Robotic-Assisted Solution is developed under DePuy Synthes standard operating procedures established and implemented in accordance with the design and development requirements as specified in ISO 13485 Cl. 7.3 utilizing methods of risk analysis in accordance with ISO 14971:2019 (Medical devices — Application of risk management to medical devices). Verification & Validation activities were performed in accordance with the product risk analysis and product requirements to demonstrate substantial equivalence with the predicate device. Where available, FDA-consensus standards and/or guidance documents were used.

Performance testing activity included:
- Intra-operative Simulated Use (Qualitative Cadaver Validation)
- Summative Usability Evaluation
- Dynamic Compensation Performance
- System Integration Test

No clinical data was necessary to support the determination of substantial equivalence.

Both the subject device and predicate device have the same intended use, same indications for use, and similar technological characteristics. Where there are technological differences, performance testing was conducted on the subject device to show that no new questions of safety or effectiveness were raised; therefore, DePuy Synthes concludes that the subject and predicate devices are substantially equivalent.