June 5, 2024

DePuy Ireland UC
Camille Chua
Regulatory Affairs Manager
Loughbeg
Ringaskiddy
Ireland

Re: K240211
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: May 6, 2024
Received: May 6, 2024

Dear Camille Chua:

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,

Shumaya Ali -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240211

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 unicompartmental knee arthroplasty.

When indicated for unicompartmental knee arthroplasty, the VELYS Robotic-Assisted Solution is indicated for use with the SIGMA HP Partial Knee Implants and INTUITION Instruments for SIGMA HP Partial Knee and their 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.

510(k) #: K240211

510(k) Summary

Prepared on: 2024-06-05

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	DePuy Ireland UC
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Correspondent Contact	Ms. Camille Chua
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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
K172301	Mako Partial Knee Application	OLO
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. 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 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 unicompartmental knee arthroplasty.

When indicated for unicompartmental knee arthroplasty, the VELYS Robotic-Assisted Solution is indicated for use with the SIGMA HP Partial Knee Implants and INTUITION Instruments for SIGMA HP Partial Knee and their 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 the predicate device have similar technological characteristics with respect to principles of operation, system design, and performance. The subject and predict device achieve the same outcomes, however the main design differences of the subject device include: image-free planning and patient anatomy assessment, robotic-assisted bone resection, and surgeon control. Performance testing on the subject device and comparison to the reference device, VELYS™ Robotic-Assisted Solution with TKA, support that there are no new questions of safety or effectiveness.

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 for Unicompartmental Knee Arthroplasty (UKA), in accordance with the product risk analysis and product requirements, in line with FDA 21 CFR Part 820, and to demonstrate substantial equivalence with the predicate device. Where available, FDA-consensus standards and/or guidance documents were used.
New bench testing specific to the expanded indication to include UKA and leveraged testing from the VELYS™ Robotic-Assisted Solution Total Knee Arthroplasty (TKA) reference device were performed for assessing device performance.

Performance testing activity included
- Sagittal Border Guard Evaluation
- Dynamic Compensation Performance Test
- Cadaveric Resection Accuracy and Soft Tissue Study
- Summative Usability Evaluation
- Design Validation

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 and VELYS™ Robotic-Assisted Solution with TKA was utilized as a reference 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.