



March 6, 2026

Depuy Ireland UC
Anuradha Moholkar
Sr. Regulatory Affairs Program Lead
Loughbeg Ringaskiddy Ireland

Re: K253551

Trade/Device Name: VELYS™ Hip Navigation
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: February 9, 2026
Received: February 9, 2026

Dear Anuradha Moholkar:

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), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 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,

A handwritten signature in black ink that reads "Jessica Lamb". The signature is written in a cursive style. A large, light blue "FDA" watermark is visible in the background behind the signature.

Jessica Lamb, Ph.D.

Assistant Director

Imaging Software Team

DHT8B: Division of Radiological Imaging Devices and
Electronic Products

OHT8: Office of Radiological Health

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.

K253551

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Please provide the device trade name(s).

?

VELYS™ Hip Navigation

Please provide your Indications for Use below.

?

VELYS™ Hip Navigation is an image-processing software indicated to assist in the positioning of total hip replacement components. It is intended to assist in precisely positioning total hip replacement components intra-operatively by measuring their positions relative to the bone structures of interest provided that the points of interest can be identified from radiology images.

VELYS™ Hip Navigation is also indicated for assisting healthcare professionals in preoperative planning and postoperative analysis of orthopaedic surgery in Total Hip Replacement and Total Knee Replacement. The device allows for overlaying of prosthesis templates on radiological images and includes tools for performing measurements on the image and for positioning the template. Clinical judgment and experience are required to properly use the software. The software is not for primary image interpretation. The software is not for use on mobile phones.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary

Submitter Information	
Applicant Name	DePuy Ireland UC
Applicant Address	Loughbeg Ringaskiddy Ireland
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Applicant Contact	Ms. Erin Combs
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Correspondent Contact	Ms. Anuradha Moholkar
Correspondent Contact Email	AMoholk1@its.jnj.com
Name of Device	
Device Trade Name	VELYST™ Hip Navigation
Common Name	Medical image management and processing system
Classification Name	System, Image Processing, Radiological
Regulation Number	892.2050
Product Code(s)	QIH, LLZ
Legally Marketed Predicate Devices	
Predicate	K160284
Predicate Trade Name	JointPoint
Product Code	LLZ; HAW

Device Description Summary

VELYST™ Hip Navigation (VHN) is a Software as a Medical Device that provides the clinician with intra-operative measurements and visuals of acetabular cup orientation, femoral component leg length and offset calculations, and implant constructs based on user-defined, but machine learning (ML) default-positioned, bony-anatomy landmark points.

VHN includes a machine learning model that places the default position of the landmark based on the output of the model; the user has full control to manipulate the landmark positions after placement. The model inputs the x-ray or fluoroscopy images and outputs a default location for the landmark annotation tool. This machine learning model is Human-in-the-Loop, as the user is expected to position the annotation as they see fit.

Intended Use/Indications for Use

VELYST™ Hip Navigation is an image-processing software indicated to assist in the positioning of total hip replacement components. It is intended to assist in precisely positioning total hip replacement components intra-operatively by measuring their positions relative to the bone structures of interest provided that the points of interest can be identified from radiology images.

VELYST™ Hip Navigation is also indicated for assisting healthcare professionals in preoperative planning and postoperative analysis of orthopaedic surgery in Total Hip Replacement and Total Knee Replacement. The device allows for overlaying of prosthesis templates on radiological images and includes tools for performing measurements on the image and for positioning the template. Clinical judgment and experience are required to properly use the software. The software is not for primary image interpretation. The software is not for use on mobile phones.

Technological Comparison

The subject device and the predicate device have similar technological characteristics with respect to principles of operation, system design, and performance. The subject and predicate device achieve the same outcomes, however the main design difference of the subject device includes a machine learning model that places the default position of a set of landmarks, where the user maintains

control and final confirmation of the landmark annotations. Performance testing on the subject device and comparison to the predicate device support that there are no new questions of safety or effectiveness.

Characteristics	Predicate Device: JointPoint K160284	Subject Device: VELYST™ Hip Navigation K253551	Discussion
Medical Specialty	Radiology	Radiology	Identical
Regulation	21 CFR 892.2050 Picture archiving and communications system	21 CFR 892.2050 Picture archiving and communications system	Identical
Product Code	LLZ System, image processing, radiological HAW Neurological stereotaxic instrument	QIH Automated radiological image processing software LLZ System, image processing, radiological	Equivalent. Both devices use anatomic landmarks identified from radiology images to assist in positioning total hip replacement components intraoperatively, and to support preoperative planning in total hip and total knee procedures
Intended Use	JointPoint is a non-invasive software (Software as a Medical Device) intended to provide preoperative templating for orthopedic procedures and intraoperative data for total hip arthroplasties (THA).	VELYST™ Hip Navigation is a non-invasive software (Software as a Medical Device) intended to provide preoperative templating for orthopedic procedures and intraoperative data for total hip arthroplasties (THA).	Identical

Indications for Use	JointPoint is an image-processing software indicated to assist in the positioning of total hip replacement components. It is intended to assist in precisely positioning total hip replacement components intra-operatively by measuring their positions relative to the bone structures of interest provided that the points of interest can be identified from radiology images. JointPoint is also indicated for assisting healthcare professionals in preoperative planning and postoperative analysis of orthopedic surgery in Total Hip Replacement, Total Knee Replacement, and Intertrochanteric Fracture Reduction. The device allows for overlaying of prosthesis templates on radiological images and includes tools for performing measurements on the image and for positioning the template. Clinical judgment and experience are required to properly use the software. The software is not for primary image interpretation. The software is not for use on mobile phones.	VELYST™ Hip Navigation is an image-processing software indicated to assist in the positioning of total hip replacement components. It is intended to assist in precisely positioning total hip replacement components intra-operatively by measuring their positions relative to the bone structures of interest provided that the points of interest can be identified from radiology images. VELYS Hip Navigation is also indicated for assisting healthcare professionals in preoperative planning and postoperative analysis of orthopedic surgery in Total Hip Replacement and Total Knee Replacement. The device allows for overlaying of prosthesis templates on radiological images and includes tools for performing measurements on the image and for positioning the template. Clinical judgment and experience are required to properly use the software. The software is not for primary image interpretation. The software is not for use on mobile phones.	Identical. The indications for use of the subject device fall within the intended use of the predicate device.
Anatomical Site and Target Population	Patients who are candidates for orthopedic procedures and total hip replacement	Patients who are candidates for total hip replacement and total knee replacement	Identical. The target population of the subject device is within that of the predicate device. There are no new questions of safety or efficacy.
Environment of Use	Physician's office and operating room	Physician's office and operating room	Identical

PRINCIPLES OF OPERATION			
Image Inputs	Preoperative and intraoperative radiographic patient images of the pelvis	Preoperative and intraoperative radiographic patient images of the pelvis	Identical
Pre-operative Analysis	Preoperative templating: • Image import • Image calibration • User selected templates of implants for THA or TKA • Digital annotations • Leg length analysis tool (THA) • Manual landmark selections	Preoperative templating: • Image import • Image calibration • User selected templates of implants for THA or TKA • Digital annotations • Leg length analysis tool (THA) • Manual landmark selections	Identical
Intraoperative Landmark Selection	• User places anatomical landmarks on patient images using digital tools (manual landmark selection) • Surgeon confirms placement of landmarks	• When enabled, an ML model determines the default landmark position. The user confirms and/or adjusts the landmark position using digital tools. This feature is available in Windows Version only. • Manual landmark selection is available as an option • Surgeon confirms placement of landmarks	Equivalent. With the subject device, when enabled, the default landmark location is determined by an ML model. In both the subject device and the predicate device, the user can move the landmark selections using digital tools, and the surgeon must confirm placement of the landmarks. Performance testing did not raise new issues of safety or efficacy.
Intraoperative Workflow Outputs	• Software provides leg length and offset data for selected implant constructs and alternatives • Software provides inclination and anteversion of the trial or final acetabular implant • Manual landmark selection	• Software provides leg length and offset data for selected implant constructs and alternatives • Software provides inclination and anteversion of the trial or final acetabular implant • Manual landmark selection or AI assisted landmarking	Identical

Other Workflows	• Contralateral overlay allows an anterior-posterior (AP) image of the non-operative side to be compared to the operative side. • OneTrial® Manual landmark selection	• Contralateral overlay allows an anterior-posterior (AP) image of the non-operative side to be compared to the operative side. • OneTrial® Manual landmark selection	Identical
Operating System	Windows, iOS	Windows, iOS	Identical. With the subject device, the AI assisted landmark placement is only available in the Windows version. The iOS version of the subject device is identical to the predicate device.

Performance Testing Summary

Machine Learning Model Validation

Data collection: The x-ray and fluoroscopic image data used for model training were extracted from the VELYST™ Hip Navigation software. Therefore, all training data are representative of expected disease state, situation, and demographics in which the clinician determined that a total hip replacement surgery with the assistance of VHN was the appropriate treatment option. Clinical institutions geographically spread across the US were strategically selected in an effort to capture the widest range of patient populations and minimize bias.

Truthing process: Training data was pulled from user data from the production VHN software. Clinicians used the software and annotated the patient images in a clinical setting. Therefore, the reference standard is the clinician's annotations for each image which was pulled with the image.

Data independence: The deidentified data used for model development consisted of 18,550 images, which was split into groups: 90% for training, 5% for validation, and 5% for test. Validation was conducted through testing on independent datasets, ensuring no overlap between training and testing data.

Model Performance Metrics: The table below summarizes the performance of three AI models evaluated for use within the VHN software. Each model was tested using a standardized dataset to assess its ability to accurately detect and localize relevant features in medical imaging. The metrics reported include:

- **mAR (mean Average Recall)**: Measures how well the model identifies all relevant instances.
- **mAP (mean Average Precision)**: Reflects the model's overall precision in predicting correct locations.
- **mAP@0.75**: Indicates precision at a higher threshold of localization accuracy.

Model	mAR	mAP	mAP@0.75
OneTrial	0.9920	0.9852	0.9900
CupCheckGuidedBilateral	0.9880	0.9798	1.0000
CupCheckGuidedUnilateral	0.9985	0.9968	1.0

Device Validation

Bench testing was performed on the subject device, VELYS Hip Navigation, in accordance with the product risk analysis and product requirements, in line with 21 CFR Part 820, and to demonstrate substantial equivalence with the predicate device. Where available, FDA-consensus standards and/or guidance documents were used.

Performance testing activity included:

1. Human vs AI System Output Validation

Validation Protocol: Human operators completed the VELYS Hip Navigation workflow for each of the test cases, manually selecting the anatomic landmarks. Output values were recorded for each test case. The AI-Assisted Landmark feature was enabled, and the workflow was completed for each of the test cases. Output values were recorded for each test case.

Acceptance Criteria: The passing criterion was for each of the 5 respective outputs (leg length, femoral offset, total offset, cup inclination, and cup anteversion), the machine learning model generated data point was within the range of the human operator data points on each of the test images.

Result: The study resulted in a Full Pass that validates the acceptance criteria stating that the machine learning model generated data points fell within the range of manual operated data points for the VELYS Hip Navigation outputs of Leg Length, Femoral Offset, Total Offset, Inclination, and Anteversion.

Workflow Efficiency: When AI-Assisted Landmarks are enabled, Human vs AI System Output Validation testing showed the time to complete the workflows took less time than the manual cases.

2. Usability Equivalency Rationale

OneTrial and Cup Check workflow iteration has been found to be safe and effective for the intended users, uses, and use environments.

DePuy Synthes performed and passed software verification and system validation testing on the device. All software requirements and risk analysis have been successfully verified and traced.

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

Conclusions

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.