



September 22, 2026

Replasia BV
% Carl Lierde
Consultant for Replasia
Aucto BV
Brusselsesteenweg 560
Meerbeke, Oost-Vlaanderen 9402
Belgium

Re: K262442
Trade/Device Name: HipStudio Analysis
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: July 20, 2026
Received: July 20, 2026

Dear Carl Lierde:

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,

A handwritten signature in black ink that reads "Jessica Lamb". The signature is written in a cursive style. In the background, there is a large, light blue, semi-transparent watermark of the letters "FDA".

Jessica Lamb, PhD
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.

K262442

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Please provide the device trade name(s).

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HipStudio Analysis

Please provide your Indications for Use below.

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HipStudio Simulation Service is an online image analysis service indicated for skeletally mature individuals that are suspected of suffering from symptomatic or asymptomatic hip conditions including but not limited to developmental dysplasia of the hip (DDH) and femoroacetabular impingement (FAI).

It enables clinicians to obtain 3D motion simulation reports based on CT image data.

The service can be used by uploading CT image data of hip joints.

The image data is processed by Replasia to create 3D anatomy models. These 3D models are then used to perform 3D motion simulations of the hip joint for different treatment approaches and to calculate bone-to-bone contact points where impingement occurs.

The HipStudio Simulation Service also calculates several morphological shape parameters for each of the 3D anatomy models.

The software generates a report as output. Clinicians do not interact with the image analysis software directly. The image analysis software is only operated by Replasia operators who have been specifically trained for this purpose. End users of the generated HipStudio Simulation Service reports are trained medical professionals, including radiologists and orthopedic surgeons.

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

☒ Prescription Use ([21 CFR 801 Subpart D](#))

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

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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)

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510(k) SUMMARY**HipStudio Simulation Service****1. Submitter Information**

Replasia BV
Interleuvenlaan 62 box 26
3001 Leuven
Belgium

Contact Person: Carl Van Lierde
Telephone Number: +32 485 71 81 85

Date Prepared: 18 July 2026

2. Device Name

Development Name (submission): HipStudio Simulation Service*
Commercial Trade Name: HipStudio Analysis
Classification Name: System, Image Processing, Radiological
Regulation Number: 21 CFR 892.2050
Device Class: Class II
Product Code: LLZ
Classification Panel: Radiology

() The device was developed under the name "HipStudio Simulatio Service" and will be marketed under the trade name "HipStudio Analysis"*

3. Predicate and reference devices

Predicate device:
Move Forward 3D Motion Simulation Service, Zimmer Biomet [K162559].

Reference device:
HipCheck, Stryker [K230045].

4. Description of Device

The HipStudio Simulation Service is an online image analysis service developed by Replasia to support the evaluation, treatment assessment and follow-up of hip conditions in skeletally mature individuals. It is primarily designed to assist with symptomatic and asymptomatic hip conditions including Developmental Dysplasia of the Hip (DDH) and Femoroacetabular Impingement (FAI).

The service aims to:

- perform detailed analyses and kinematic simulations of the patient's anatomy, generating clinically relevant data for assessing hip conditions.
- simulate treatment approaches for various hip conditions, including surgical procedures like the removal of bone parts for FAI. It also supports non-surgical treatments.

The service workflow consists of three steps:

1. Case creation and incoming data inspection
2. Image segmentation and 3D model generation
3. HipStudio analysis and treatment assessment

Case creation and incoming data inspection

The HipStudio Simulation Service uses the *LiquidFiles* software application for communication and data exchange with the treating physician. Clinical cases are initiated by the treating physician through the secure file transfer portal, which supports end-to-end encryption and full audit logging. Upon upload, imaging data (i.e. CT scan data) are transmitted via encrypted channels and stored in a controlled-access environment.

Authorized, trained Replasia personnel access the data to perform an initial technical quality check to confirm suitability for the intended analysis.

Immediately thereafter, all datasets undergo a structured pseudonymization process using Mimics software from Materialise [K073468], in which direct identifiers are removed or replaced. Following successful pseudonymization, the original identifiable files are permanently deleted in accordance with data minimization policies.

All processing steps are conducted under strict access controls and user authentication to ensure compliance with applicable data protection and medical data security requirements.

Image segmentation and 3D model generation

The pseudonymized CT images are processed by Replasia using *Mimics* software from Materialise [K073468]. During this step, the anatomical structures of the hip are delineated in the grayscale images, based on Hounsfield units, texture and shape. Next, three-dimensional representations (i.e. 3D models) of said structures are calculated by the software. These serve as input for the third and final step.

HipStudio analysis and treatment assessment

In this step, proprietary Replasia software, HipStudio is used by trained Replasia personnel to analyze the joint's morphology, perform kinematic simulations and virtually simulate (surgical and/or non-surgical) hip preservation treatments using the previously generated three-dimensional representations of the hip anatomy. Clinicians do not interact with the analysis software directly.

HipStudio generates a comprehensive digital report based on the performed analyses. The report is shared with the treating physician through the *LiquidFiles* platform. If necessary, a separate online session is organized to discuss the results of the analysis with the surgeon.

5. Indications for Use:

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The service can be used by uploading CT image data of hip joints.

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6. Substantial Equivalence:

Element	HipStudio	Forward 3D Motion (predicate)
Nature of the service	Service to support—but not replace—clinical judgment in diagnosing and treatment planning of hip conditions by delivering of a report containing: - calculated morphological parameters (quantitative measures) of the hip anatomy 3D motion simulation analysis results (incl. range of motion)	Service to support—but not replace—clinical judgment in diagnosing and treatment planning of hip conditions by delivering of a report containing: - calculated morphological parameters (quantitative measures) of the hip anatomy 3D motion simulation analysis results (incl. range of motion)
Role in clinical workflow	Analysis of medical images	Analysis of medical images
Input	CT images of the hip joint.	CT and/or MRI images of the hip joint.
Output characteristics	- Automated report generation in .pdf format. - Structured report containing measurements presented in graphical format including annotations on images	- Automated report generation in .pdf format (with embedded; interactive 3D viewer). - Structured report containing measurements presented in graphical format including annotations on images
Key functions	- Femoral head coverage - Femur morphology - Acetabulum morphology - Pelvic orientation - Range of motion - CAM Deformity Assessment incl. alpha-angle	- Femoral head coverage - Femur morphology - Acetabulum morphology - Pelvic orientation - Range of motion - CAM Deformity Assessment incl. alpha-angle

Processing logic	• Cloud-based case communication and data exchange (LiquidFiles) • Image segmentation and 3D model generation (Mimics software from Materialise K073468). • Morphological analysis and treatment assessment (HipStudio software) • Report generation (HipStudio software) • Report delivery (Liquidfiles)	• Cloud-based case communication and data exchange (Forward 3D Motion) • Image segmentation and 3D model generation • Morphological analysis and treatment assessment (Forward 3D Motion) • Report generation (Forward 3D Motion) • Report delivery
Core algorithms (in analysis software)	• By default the pelvis is kept in the as-scanned (typically supine) position for the analyses. A correction of the pelvis orientation can be applied if desired to simulate a corrected standing or other functional position, using the measured spinopelvic tilt on X-Ray in that position. • The femur orientation is corrected to a neutral position following the ISB hip joint coordinate system, before the analyses are performed.	• Before the analyses are performed, the pelvis orientation is corrected following the ISB hip joint coordinate system. • The femur orientation is corrected to a neutral position following the ISB hip joint coordinate system, before the analyses are performed.
	• Femoral head coverage calculated as a true 3D coverage by (i) drawing lines through each point on the acetabular rim on one hand and the femoral head center on the other hand, and calculating the intersecting points of these lines with the sphere fitted on the femoral head, (ii) connecting the intersecting points by a curve to mark the coverage on the sphere. The percentage coverage is computed between the surface area of the projected curve and the total sphere surface area.	• Femoral head coverage calculated by projecting acetabular rim points toward the femoral head center and onto the horizontal plane, forming a curved line across the projected sphere fitted on the femoral head. The percentage coverage is computed from the overlap area between the curve and circle.
	• Lateral center edge angle calculated at the 12 o'clock (vertical) position. • Measurement of Tonnis angle / Sourcil angle, using 3D landmarks	• The LCEA is measured at 3 discrete positions: 11, 12 and 1 o'clock. • Measurement of Tonnis angle / Sourcil angle, using landmarks identifiable on a 2D radiograph
	• Determination of femoral head diameter by fitting a sphere onto the femoral head surface	• Determination of femoral head diameter by fitting a sphere onto the femoral head surface

	• Measurement of the 2D acetabular version as the angle between a line connecting the anterior acetabular margin with the posterior acetabular margin in the 2D plane, and the sagittal/anteroposterior axis. • Measurement of 3D acetabular anteversion by defining the acetabular axis as the weighted average of normal vectors within the acetabular cavity. The anteversion is then calculated as the angle between this axis projected in the transverse plane and the coronal plane.	• Measurement of (2D) acetabular anteversion utilizing digital reconstructed radiographs to determine the version in a 2D horizontal plane. Acetabular version is measured as the angle between a line connecting the anterior acetabular margin with the posterior acetabular margin in the 2D plane, and the sagittal/anteroposterior axis.
	• Range of motion simulation using the Equidistant Method (<i>"The Equidistant Method – a novel hip joint simulation algorithm for detection of femoro-acetabular impingement"</i>, Marc Puls et al. <i>Computer Aided Surgery</i>, August–December 2010; 15(4–6): 75–82)	• Range of motion simulation using the Equidistant Method (<i>"The Equidistant Method – a novel hip joint simulation algorithm for detection of femoro-acetabular impingement"</i>, Marc Puls et al. <i>Computer Aided Surgery</i>, August–December 2010; 15(4–6): 75–82)
	• Pincer FAI: the excess bone on acetabular side potentially causing FAI is determined by comparing the marked acetabular rim with the acetabular rim shape of healthy hip joints as reported in scientific literature. • CAM FAI: the excess bone on the proximal femur side that potentially causes FAI is determined by comparing the shape of the patient's proximal femur with that of the reconstructed healthy shape of the proximal femur for that specific patient. The reconstructed healthy shape is generated by a validated Statistical Shape Model, trained with healthy proximal femur shapes.	• Pincer and CAM FAI: the excess bone on acetabular and femur side is calculated by simulating hip joint rotation to desired rotation angles and calculating the overlap bone between acetabulum and proximal femur. The desired rotation angles are based on the average range of motion of healthy hip joints.
Deployment and Delivery Mechanism	Service using a controlled-access web interface (LiquidFiles)	Online service, access via web portal (Forward 3D Motion)
Interface usability and interaction	• Interaction through the LiquidFiles web interface • Static .pdf report	• Interaction through the Forward 3D Motion web interface • .pdf report with interactive 3D viewer

Throughput time for service	3 days	Unknown (services no longer commercially offered)
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7. Non-Clinical Performance Data.

The non-clinical performance of the HipStudio Simulation Service was evaluated through a comprehensive V&V program conducted in accordance with applicable FDA guidance for quantitative imaging devices, recognized consensus standards, and Replasia's quality management system.

The HipStudio Simulation Service incorporates three software applications within its workflow: LiquidFiles, Mimics, and HipStudio. LiquidFiles is a commercially available secure file transfer application used for encrypted communication between Replasia and the treating physician. Mimics (Materialise NV; FDA-cleared under K073468) is a commercially available medical image processing software application used for pseudonymization, image segmentation, and generation of patient-specific three-dimensional anatomical models from CT and/or MR image data. HipStudio is proprietary software developed by Replasia and is used by trained Replasia personnel to perform anatomical measurements, kinematic simulations, impingement analyses, and generation of the HipStudio Simulation Service report.

The HipStudio software was developed in accordance with IEC 62304:2006+A1:2015 and has been classified as Moderate Level of Concern software consistent with applicable FDA guidance. Software verification and validation activities were performed for the commercial release version (v1.4) and included functional verification, verification of generated report outputs, and cybersecurity verification.

Technical performance testing included evaluation of segmentation accuracy, algorithmic accuracy, repeatability, reproducibility, statistical shape model validation, report output verification, usability validation, clinical association validation, and predicate output equivalence.

Segmentation accuracy was supported by published validation studies demonstrating sub-millimeter accuracy of the upstream segmentation process performed using Mimics. Algorithmic accuracy testing using a Digital Reference Object demonstrated exact agreement between software-generated measurements and predefined ground truth values. Repeatability and reproducibility testing demonstrated acceptable precision and consistency for evaluated quantitative measurements and simulation outputs.

Clinical association was established through a structured literature-based clinical association matrix that mapped each reported parameter and simulation output to established clinical concepts used in the assessment and treatment planning of hip disorders. The clinical association matrix was independently reviewed by six experienced orthopedic hip surgeons, all of whom confirmed that the reported parameters are clinically recognized, relevant to hip morphology assessment and treatment planning, and presented in a clinically interpretable manner.

Usability testing demonstrated that intended users could correctly interpret the information presented in the generated reports. Predicate output equivalence testing demonstrated comparable report content, quantitative measurements, and clinical information between the

HipStudio Simulation Service and the predicate device. Collectively, the non-clinical performance testing demonstrated that the HipStudio Simulation Service performs as intended and provides accurate, reliable, and clinically relevant quantitative outputs to support the assessment, simulation, and preoperative planning of hip conditions.

The non-clinical performance testing demonstrated that the HipStudio Simulation Service performs as intended. The results support the accuracy and reliability of the generated measurements, simulation outputs, and reports and demonstrate that the device provides information that is technically valid, clinically associated with established orthopedic concepts, and appropriate to support qualified healthcare professionals in the assessment and preoperative planning of hip conditions within the device's intended use.

8. Clinical Performance Data.

No data from human clinical studies has been included to support the substantial equivalence of the HipStudio Simulation Service.

9. Conclusion Regarding Substantial Equivalence

Based on comprehensive non-clinical evaluation, including bench testing, software verification and validation, and analytical performance assessments, the HipStudio Simulation Service has been demonstrated to meet all predefined acceptance criteria and applicable standards. The results confirm that the device performs as intended under expected conditions of use, with accuracy, reliability, and reproducibility comparable to those of the identified predicate device i.e. Move Forward 3D Motion Simulation Service [K162559].

No new or increased risks were identified, and all potential hazards have been appropriately mitigated through design controls and risk management measures.