March 31, 2023

Formus Labs, Ltd
% Richie Christian
Head of Regulatory and Quality
Suite 5, Floor 3, 30 St Benedicts Street
Eden Terrace
AUCKLAND 1010
NEW ZEALAND

Re: K213272
Trade/Device Name: Formus Hip
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: February 23, 2023
Received: February 23, 2023

Dear Richie Christian:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For

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

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.

510(k) Number *(if known)*
K213272

Device Name
Formus Hip

Indications for Use *(Describe)*
Formus Hip is a pre-operative planning software for orthopedic surgery. The standalone software application imports patient diagnostic imaging studies (e.g. pre-dimensioned CT scans) from PACS-systems or other conventional medias. The Formus Hip system contains an integrated database of orthopedic hip implant geometries that can be overlayed to assist surgeons in their planning of orthopedic hip surgeries. The software application further enables the healthcare professional to customize their preoperative planning by means of an interactive graphical user interface. Finalized plans can be printed to a PDF report. The qualified healthcare professional can digitally perform the surgical planning and also make it available as a printable report. Clinical judgment and experience with the software are required for its successful 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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1. SUBMITTER

Formus Labs Ltd.
Suite 5, Floor 3, 30 St Benedicts Street
Eden Terrace
Auckland 1010
New Zealand

Contact Person: Richie Christian, Head of Regulatory and Quality
Email: richie@formuslabs.com

Last Updated: 31 March 2023

2. DEVICE

Name of Device:	Formus Hip
Classification Name:	Medical image management and processing system
Common Name:	Orthopedic Pre-operative Planning Software
Regulation:	21 CFR §892.2050
Regulatory Class:	II
Product Code:	QIH

3. PREDICATE DEVICE

PeekMed (K182464)
This predicate has not been subject to a design-related recall.

4. DEVICE DESCRIPTION

Formus Hip is a semi-automated Software as a Medical Device (SaMD) that allows pre-operative planning of primary total hip arthroplasty in real time using the Zimmer Biomet Taperloc G7 system. Using a series of algorithms, the software creates a 3D model and relevant measurements derived from the patient's pre-dimensioned CT scan. Formus Hip generates a 3D model without any user input. Additional algorithms fit the femoral stem and acetabular cup based on the patient anatomy. The software allows the user to adjust the plan interactively to achieve the desired clinical targets.

Formus Hip uses an AI-based automatic image segmentation algorithm trained on CT scans of male and female subjects with typical and atypical bony anatomy between the ages of 21 and 94. Formus Hip also uses statistical shape models of the femur and pelvis trained on segmented 3D models of male and female subjects with typical and atypical bony anatomy between the ages of 18 and 89.

The training datasets are independent from testing and validation datasets. Training data and internal testing data are tracked in a single record file under version control where they are labelled as either training or testing. Code used for training and testing is read from this record file so that a data point is never mixed between the training and testing datasets. Validation data was sourced from different geographies and stored in locations separate from training and internal testing data to ensure independence.

5. INTENDED USE

Formus Hip is a preoperative surgical planning software. It is intended to assist qualified medical professionals in the preoperative planning of orthopedic surgical procedures.

6. INDICATIONS FOR USE

Formus Hip is a pre-operative planning software for orthopedic surgery. The standalone software application imports patient diagnostic imaging studies (e.g. pre-dimensioned CT scans) from PACS-systems or other conventional medias. The Formus Hip system contains an integrated database of orthopedic hip implant geometries that can be overlayed to assist surgeons in their planning of orthopedic hip surgeries. The software application further enables the healthcare professional to customize their preoperative planning by means of an interactive graphical user interface. Finalized plans can be printed to a PDF report. The qualified healthcare professional can digitally perform the surgical planning and also make it available as a printable report. Clinical judgment and experience with the software are required for its successful use.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE

The table below provides a comparison of the technological characteristics of Formus Hip and the legally marketed predicate device (PeekMed, K182464).

Device	**Subject Device** **Formus Hip** **(K213272)**	**Predicate Device** **PeekMed** **K182464**
Manufacturer	Formus Labs Ltd.	Peek Health, S.A.
Product Code	QIH	LLZ
Regulation Number	21 CFR 892.2050	21 CFR 892.2050
Regulation Name	System, Image Processing, Radiological	System, Image Processing, Radiological
Intended Use	Formus Hip is a preoperative surgical planning software. It is intended to assist qualified medical professionals in the preoperative planning of orthopedic surgical procedures.	PeekMed is a preoperative planning software for surgery
Indications for Use	Formus Hip is a pre-operative planning software for orthopedic surgery. The standalone software application imports patient diagnostic imaging studies (e.g. pre-dimensioned CT scans) from PACS-systems or other conventional medias. The Formus Hip system contains an integrated database of orthopedic hip implant geometries that can be overlayed to assist surgeons in their planning of orthopedic hip surgeries. The software application further enables the healthcare professional to customize their preoperative planning by means of an interactive graphical user interface. Finalized plans can be printed to a PDF report. The qualified healthcare professional can digitally perform the surgical planning and also make it available as a printable report. Clinical judgment and experience with the software are required for its successful use.	PeekMed is a software system designed to help surgeons' specialists carry out the preoperative planning in a prompt and efficient manner for several surgical procedures, based on their patients' imaging studies. The software imports diagnostics imaging studies such as x-rays, CT or magnetic resonance image (MRI). The import process can retrieve files from a CD ROM, a local folder or the PACS. In parallel, there is a database of digital representations related to prosthetic materials supplied by their producing companies. PeekMed allows health professional to digitally perform the surgical planning without adding any additional steps to that process. This software system requires no imaging study acquisition specification (no protocol). Experience in usage and a clinical assessment are necessary for a proper use of the software.

Device	Subject Device Formus Hip (K213272)	Predicate Device PeekMed K182464
Patient Population	Adults (≥ 21 years)	Adults and pediatrics
End Users	Qualified medical professionals	Surgeons
Computer	Personal computer or workstation	Personal computer or workstation
Operating System	Windows with a Chrome browser	Windows or OS X
Radiological Image Format	DICOM	DICOM
Device Availability	Can be accessed from the Chrome internet browser launched from a standalone PC or workstation with internet access.	It can be set to start from a workstation or standalone for planning procedures.
Image Source	Receive digital images from various sources (including PACS system)	Receive digital images from various sources (including PACS system)
Data Processing	The software processes pre-dimensioned CT imaging to produce digital representations of the patient anatomy to which digital representations of prosthetic components are overlapped.	The software processes data in order to provide an overlap and dimensioning of digital representations of the prosthetic material
Digital Overlap of Prosthetic Material	Allows the overlap of the digital representation of prosthetic components	Allows the overlap of models and the intersection of the models
Interactive Model Positioning	Yes	Yes
Interactive Model Dimensioning	Yes	Yes
Model Rotation	Yes	Yes
Support for Digital Prosthetic materials Provided by the Manufacturers	Yes	Yes
Anatomical Landmarks	Yes	Yes
Medical Subspecialities	Hip	Hip, Knee, Spine, Upper Limb, Foot-and-Ankle, Trauma
Pre-specified Procedures	Total Hip Arthroplasty	Total Hip Arthroplasty (Additional joint replacements and associated procedures specific to product intended for expanded indications)
Pre-surgical Planning	Yes	Yes
Contact with the Patient	No	No
Control of Life Supporting Devices	No	No
Human Intervention for Image Interpretation	Yes	Yes
Ability to Add Additional Modules When Available	Yes	Yes

8. NON-CLINICAL PERFORMANCE DATA

Software verification and validation was performed per Formus Labs' design and development processes which confirmed that the product specifications have been met. Formus Hip is classified as a "moderate" level of concern since a failure or latent flaw could indirectly result in minor injury to the patient.

Dedicated system verification testing including but not limited to automated tests, manual tests and regression tests has been performed against pre-defined acceptance criteria. Each test met its predefined acceptance criteria for all functions of the software.

Dedicated validation has been performed on image processing accuracy and implant sizing, as below.

Image Processing Accuracy

Dedicated validation has been performed on 60 images acquired (from 60 patients) in the US to validate accuracy of image processing by comparing automatically generated 3D models of the femur and hemipelvis to the 3D models generated via manual segmentation by a panel of US radiologists. The images were acquired on Philips – Brilliance Big Bore, LightSpeed16, and LightSpeed VCT using Formus Labs' standard CT protocol. The demographic distribution of this dataset is provided below.

- Gender: Male: 34; Female: 26
- Age: Minimum: 41; Maximum: 88
- Ethnicity: Black or African American: 18; Hispanic: 16; White: 16; Not specified: 10

Ground truth was obtained by US-board registered radiologists (truthers) experienced in 3D image segmentation. Each bone surface was manually segmented by two radiologists. A third senior radiologist reviewed each pair of segmentation and selected the most accurate segmentation which was the final manually segmented mesh.

Difference between the automatic (Formus Hip generated) and manual 3D models were quantified using the Sorensen-Dice coefficient (Dice), Mean Absolute Distance (MAD) and Hausdorff Distance (HD). All acceptance criteria were met, as shown in the table below.

Endpoint	Acceptance Criteria	Results
3D models from image segmentation	The average Dice score must be equal or greater than 0.9	Hemipelvis: 0.95 Femur: 0.97
	The average MAD must be equal or less than 2 mm	Hemipelvis: 1.15 Femur: 1.35
	The average HD must be equal or less than 5 mm in the femoral head and acetabulum	Femoral head: 2.84 Acetabulum: 3.04
3D models of the proximal shaft inner cortical surface	The average MAD must be equal or less than 2 mm	Inner cortical surface: 1.02
	The average HD must be equal or less than 5 mm	Inner cortical surface: 2.80
3D models generated from statistical shape modelling	The average Dice score must be equal or greater than 0.9	Hemipelvis: 0.95 Femur: 0.97
	The average MAD must be equal or less than 2 mm	Hemipelvis: 1.25 Femur: 1.49
	The average HD must be equal or less than 5 mm in the femoral head and acetabulum	Femoral head: 2.47 Acetabulum: 2.93

Consistency in performance across all subgroups (i.e., sex, age, body mass index, ethnicity, and CT scanner) was assessed to demonstrate generalisability of the device across the intended US patient population.

Implant Sizing

A validation on implant sizing was performed on 133 images (from 133 patients) in Australia in which the implant sizes recommended by Formus Hip were compared to the implant sizes (ground truth) determined by orthopaedic surgeons. The images were acquired via a variety of common clinical CT scanners using Formus Labs' standard CT protocol. The demographic distribution of this dataset is provided below.

- Gender: Male: 70; Female: 63
- Age: Minimum: 42; Maximum: 87

Ground truth was obtained by orthopaedic surgeons (truthers) using traditional templating methods. The different in sizes recommended by Formus Hip was compared with ground truth. The performance goal was that at least 80% of cup and stem sizes recommended by Formus Hip were within ±2 sizes of the ground truth.

The acceptance criteria were met as the proportion of stems and cups recommended by Formus Hip that were within 2 sizes of ground truth were 94% (95% CI 0.947 – 0.998) and 98% (95% CI 0.885 – 0.974), respectively.

9. CLINICAL PERFORMANCE DATA

Substantial equivalence was not based on an assessment of clinical performance data.

10. CONCLUSIONS

Formus Hip has the same intended use, indications for use, technological characteristics and principles of operation compared to the predicate device and does not raise different questions of safety or effectiveness.