Vent Creativity
Craig Vittorio
Director of Product / QARA
101 6th Ave
3rd Floor
New York, New York 10013

March 20, 2025

Re: K241961
Trade/Device Name: Vent Creativity Knee v1.0 (Hermes)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: February 18, 2025
Received: February 18, 2025

Dear Craig Vittorio:

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.

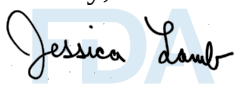
All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (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,



Jessica Lamb, PhD
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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)*

K241961

Device Name

Vent Creativity Knee v1.0 (Hermes)

Indications for Use *(Describe)*

Hermes is intended for use as a software interface and image segmentation system for the transfer of medical imaging information to an output file. It is also intended as preoperative software for diagnostic and surgical planning.

For these purposes, output files can also be used for the fabrication of physical replicas using traditional or additive manufacturing methods. The physical replicas can be used for diagnostic purposes in the field of orthopedic applications.

The software is intended to be used in conjunction with other diagnostic tools and expert clinical judgment.

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) #: K241961

510(k) Summary

Prepared on: 2025-03-13

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Vent Creativity
Applicant Address	101 6th Ave 3rd Floor New York NY 10013 United States
Applicant Contact Telephone	203-814-7954
Applicant Contact	Mr. Craig Vittorio
Applicant Contact Email	cvittorio@ventcreativity.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Vent Creativity Knee v1.0 (Hermes)
Common Name	Hermes
Classification Name	Automated Radiological Image Processing Software
Regulation Number	892.2050
Product Code(s)	QIH, LLZ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K203195	Simpleware ScanIP Medical	LLZ

Device Description Summary

21 CFR 807.92(a)(4)

Vent Hermes takes DICOM based CT scans from the scanning machine and plots the data generated by the machine in the form of slices of data, similar to all commercially available predicates.

The intensity data (Hounsfield Unit data) inside these features is displayed to ensure that all intensity data is visible to the users. The point clouds from these data points are used to find landmarks in discrete locations, unlike the predicates that use bone outlines from automatic or semi automatic or manual sources to generate points for landmarks. This approach allows for more accurate predictions, as validated in previous studies by radiology experts. Published literature is used to define the 3 cut plane philosophies for the bones where proximal tibia and distal and posterior femoral cuts are calculated.

The product does not currently make any claims of individual implant fits but gives the initial cut planes shared by all surgeon and implant manufacturers as the first step. The python code has been developed with a design history file with design iterations recorded on all major changes to the system. The segmentation aspect is a Convolutional Neural Networks model trained with arthritic CT scans from 120 de-identified patients with varying arthritic states, demographics, and CT machines and centers partnering with surgeon champions.

The segmentation and landmarking system was validated against manual, Materialize Mimics 24 autosegmentaiton, and Synopsys Simpleware knee auto segmentation models, and results were reviewed with the Chief of Radiology of Hospital for Special Surgery in New York, NY. The results were published in the International Society for Technology in Arthroplasty 2022 annual conference. Vent Hermes is a cloud-based python code that allows users to upload the de-identified DICOM files to their encrypted Google Cloud Platform folder (a business agreement certified partner with HIPAA and 21 CFR 11 certifications available).

Once the files are uploaded, the cloud server de-identifies the folder again for redundant safety, then passes it to Vent Creativity's internal server for the system to automatically run the scripts to generate the bone models, landmarks, and the final cut planes and returns these files to the user folder under the same file number. Once the point clouds, meshes, and landmarks are calculated, any number of CAD or visualization tools can be used to review the data.

The system uses a custom UI generated on the OHIF medical imaging platform with system version controls and validation documents on file. This portion is considered to be software outside of the medical device as no calculation is allowed outside the python code. The visualizations are final and are for user review and approval only.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

Hermes is intended for use as a software interface and image segmentation system for the transfer of medical imaging information to an output file. It is also intended as preoperative software for diagnostic and surgical planning.

For these purposes, output files can also be used for the fabrication of physical replicas using traditional or additive manufacturing methods. The physical replicas can be used for diagnostic purposes in the field of orthopedic applications.

The software is intended to be used in conjunction with other diagnostic tools and expert clinical judgment.

Indications for Use Comparison 21 CFR 807.92(a)(5)

Simpleware ScanIP Medical is intended for use as a software interface and image segmentation system for the transfer of medical imaging information to an output file. It is also intended as preoperative software for diagnostic and surgical planning.

For these purposes, output files can also be used for the fabrication of physical replicas using traditional or additive manufacturing methods. The physical replicas can be used for diagnostic purposes in the field of orthopedic, maxillofacial and cardiovascular applications.

The software is intended to be used in conjunction with other diagnostic tools and expert clinical judgment.

Technological Comparison 21 CFR 807.92(a)(6)

ScanIP operates using foundational technologies to handle image processing and the creation of models. In contrast, Vent Hermes incorporates state-of-the-art algorithmic techniques to bolster both precision and speed. During the Verification and Validation stages of its development, comprehensive tests were carried out on Vent Hermes to ascertain that the DICOM file interpretations were as consistent and precise as those produced by the predicate, ScanIP.

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

Substantial equivalence was evaluated in software validation reports pertaining to accuracy of the segmentation and subsequent DICE score comparison to previously marketed devices under the same regulation. See V&V section for DICE Validation Reports.

N/A

Conclusions from the Nonclinical and Clinical Tests
The nonclinical and clinical tests performed as part of the Segmentation Analysis and DICE Score Study have provided a comprehensive assessment of the Hermes Segment Knee Neural Network Task. The study compared the segmentation accuracy of Hermes with two predicate segmentation tools, Synopsys and Mimics, using the Dice Similarity Coefficient (Dice score) as the primary metric.

Safety and Effectiveness
The Hermes Segment Knee Neural Network Task was evaluated against stringent design and software requirements, including the ability to accurately identify and segment relevant bones (femur, fibula, tibia, and patella) from DICOM CT scan files. The study confirmed that Hermes met these requirements without introducing unintended bone segmentations.

The nonclinical and clinical tests conducted for the Hermes Segment Knee Neural Network Task demonstrated that it meets essential safety and effectiveness criteria, effectively identifying and segmenting relevant bones from DICOM CT scans without unintended segmentations. When compared to the two predicate tools, Synopsys and Mimics, Hermes demonstrates substantial equivalence.