Synopsys (Northern Europe) Ltd.
% Ms. Jessica James
Business Process Analyst
Bradninch Hall, Castle Street
Exeter, Devon EX4 3PL
UNITED KINGDOM

April 1, 2021

Re: K203195
Trade/Device Name: Simpleware ScanIP Medical
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: October 26, 2020
Received: October 28, 2020

Dear Ms. James:

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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

6. Indications for Use Statement (Form FDA 3881)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

~~Not known~~ K203195

Device Name

Simpleware ScanIP Medical

Indications for Use *(Describe)*

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 pre-operative 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.

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.

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FORM FDA 3881 (7/17) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

4.3. Updated 510(k) Summary

K203195

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Contact person: Jessica James

Summary prepared: 1st March, 2021

II. DEVICE

Trade name: Simpleware ScanIP Medical; Simpleware ScanIP; ScanIP Medical, Simpleware ScanIP 3DP; Simpleware Scan3DP

Common name: Image processing system and preoperative software for simulating and evaluating surgical treatment options

Classification name: Picture Archiving and Communications System (21 CFR 892.2050)

Regulatory Class: II

Product Code: LLZ

Panel: Radiology

III. PREDICATE DEVICE

Substantial equivalence is claimed between Simpleware ScanIP Medical and the following legally marketed device:

- Simpleware ScanIP (K142779).

Please note that the predicate device applicant 'Simpleware Ltd' and the subject device applicant Simpleware Product Group, Synopsys Northern Europe Ltd., are the same manufacturer – the change in name is the result of Simpleware Ltd. being acquired by Synopsys in 2016. The current device and facility listing for the predicate device is for the Simpleware Product Group, Synopsys Northern Europe.

Device Description

Simpleware ScanIP Medical is image processing software that enables users to import, visualize, and segment medical images, and export digital 3D models. These models can be used in the software for pre-surgical tasks, and can also be used to produce output files suitable for additive manufacturing (3D printing). Simpleware ScanIP Medical also has functionality for transferring from and to third-party software packages.

Simpleware ScanIP Medical is a modular product, including the following functionalities:

- Import of medical images in various formats

- Transferring files from and to computer-aided design (CAD) software packages
- Image filtering and segmentation tools
- 2D and 3D visualization of image data and CAD drawings
- Analysis, measurements, and statistics from 3D image data and CAD drawings
- Generating and exporting meshes to Finite Element (FE) packages.
- Generating and exporting models to CAD software
- Support for scripting in a number of programming languages

Indications for Use

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 pre-operative 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.

Indications for Use Comparison

There are differences between the Indications for Use for the subject and predicate device.

Similarities include:

- The general purpose of diagnostic planning and pre-surgical planning remains the same
- There is no change in stated safety and effectiveness

The differences in the Indications for Use exist between the subject and predicate device will be presented and discussed below:

- The introduction of new intended applications is motivated by the expanded scope for 3D printing that can be used for diagnostic planning.
- The wording in the previous predicate statement on ‘simulating/evaluating surgical treatment options’ has also been rephrased to “pre-operative software for measuring and treatment planning” to more clearly explain the device’s diagnostic function. However, the meaning is the same.
- The description in the predicate device of transferring ‘imaging information from a medical scanner such as a CT scanner or Magnetic Resonance Imaging scanner’ has been simplified to ‘the transfer of medical imaging to an output file’, to reflect changes in state-of-the-art for the scope of uses of the software technology.

Comparison of Technological Characteristics with Predicate Device

Detailed comparison between the subject and predict devices show that the subject device is substantially equivalent in intended use, design, functionality, operating principles, and performance characteristics to the predicate.

The technological similarities between the subject and predicate devices are:

- Both predicate and subject devices are versions of the same software
- Both predicate and subject devices are software interface and image segmentation systems for transferring medical imaging information to an output file, with the goal of being used as pre-operative software, and for measuring and treatment planning
- Both predicate and subject device are considered to have a ‘Moderate’ Level of Concern

- Both devices have equivalent image segmentation, measurement and model generation functionality
- The subject device is a later version of the predicate device, following the same development practices and testing procedures, with verification and validation covering the same areas
- Validation of the subject device shows it to be equivalent in performance to the predicate device

The following technological differences exist between the subject and predicate device:

- Due to the change in scope of the intended use, the subject device's documentation explicitly references and provides a validation method for the 3D printing of output files for diagnostic purposes in orthopedic, maxillofacial, and cardiovascular applications, whereas this was previously excluded in the predicate device
    - An additional hazard has also been created to reference specific risks and mitigation actions for this purpose
- Supported platforms: in addition to Microsoft Windows, the subject device is supported on Linux.
- Minor software changes (when it comes to addressing the intended use) exist between the two versions of the same software

Performance Data

Software verification and validation were carried out based on the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", including verification against defined requirements, validation to intended use, and bench testing.

Validation was carried out for the workflow of going from 3D image to printed model, demonstrating that the anatomical models for cardiovascular, orthopedic, and maxillofacial applications can be printed accurately when using compatible 3D printers. The intention of this testing is to demonstrate that the expanded scope does not raise new issues of safety and performance.

Nonclinical Tests Relied on for Determination of Substantial Equivalence

Simpleware ScanIP Medical has been bench-tested for its intended use to determine substantial equivalence to the predicate device, including for validating measurement and model accuracy.

Clinical Tests Relied on for Determination of Substantial Equivalence (if available)

No clinical tests were conducted to determine substantial equivalence.

Conclusions

The characteristics determining functionality and performance of Simpleware ScanIP Medical are substantially equivalent to the device cleared under K142779:

- Technological differences between the subject and predicate devices are non-substantial both in terms of functional differences and product development processes
- Non-clinical bench-testing results demonstrate that the subject device is as safe, effective, and functional as the predicate device
- The subject device's intended use is still broadly the same as the predicate device, functioning as a software interface and image segmentation system for the transfer of medical imaging information to an output file, and as pre-operative software for diagnostic and surgical planning.
- The change in indications for use to explicitly include use of output files for diagnostic 3D printing is supported by validation testing