May 30, 2023

DASISimulations
Lakshmi Dasi
Chief Technology Officer
5115 Parkcenter Ave
Suite 205
Dublin, Ohio 43017

Re: K223809
Trade/Device Name: PrecisionTAVI (v1.1)
Regulation Number: 21 CFR 870.1405
Regulation Name: Interventional cardiovascular implant simulation software device
Regulatory Class: Class II
Product Code: QQI
Dated: December 19, 2022
Received: April 26, 2023

Dear Dr. Dasi:

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,

Jaime Raben -S

Jaime Raben, PhD
Acting Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
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)*
K223809

Device Name
PrecisionTAVI v1.1

Indications for Use *(Describe)*

PrecisionTAVI is an optional, non-invasive, post processing software solution that is indicated for patient-specific simulations of Transcatheter Aortic Valve Replacement (TAVR) during procedural planning.

The software performs computer simulation to predict post TAVR in vivo valve frame deformation of clinician selected Transcatheter Heart Valve (THV) device types and sizes.

The information provided by PrecisionTAVI is intended for use by cardiologists, radiologists, and clinical specialists, and is not intended in any way to eliminate, replace, or substitute for, in whole or in part, the healthcare provider's judgment and analysis of the patient's condition. The clinician receiving the images retains the responsibility for interpreting and validating all information and making all patient treatment decisions.

PrecisionTAVI is not intended to replace the simulated device's instructions for use for final TAVR device selection and placement.

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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K223809 510(K) SUMMARY

SUBMITTER

Company Name:	DASI Simulations
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Contact:	Lakshmi Prasad Dasi
Phone number:	614-586-6760
Email:	lakshmi.dasi@dasisim.com
Date prepared	May 26, 2023

DEVICE

Device Name:	PrecisionTAVI
Classification Name:	Interventional Cardiovascular Implant Simulation Software Device
Regulation Number:	870.1405
Product Code:	QQI

PREDICATE DEVICE

Predicate #	K214066
Device Name:	FEops HEARTguide
Product Code:	QQI

DEVICE DESCRIPTION

DASI Simulations PrecisionTAVI is a computer simulation device that predicts implant frame deformation after implantation of a Transcatheter Heart Valve (THV) device. The simulation combines a predefined THV device model and size with a patient-specific model of the patient's anatomy thereby predicting the post deployment deformation of the THV and the anatomy. The simulation results are intended to be used by qualified clinicians as additional information for planning transcatheter aortic valve replacement (TAVR).

PrecisionTAVI conducts TAVR device deployment simulation using proprietary computational modeling technology.

The input for the simulation is a 3D model of the patient anatomy. The 3D model is generated from 2D medical images of the patient anatomy (multi-slice Cardiac Computed Tomography).

The simulation output is a report with 3D visualization capability to depict the predicted deformed THV in the deformed patient-specific anatomy of the aortic valve and root.

The 3D model generation and the report generation from the simulation is performed by trained operators at DASI Simulations using an established workflow. The report is accessible to the end user as a download from the DASI Simulations portal with a standard web browser.

INDICATIONS FOR USE

PrecisionTAVI is an optional, non-invasive, post processing software solution that is indicated for patient-specific simulations of Transcatheter Aortic Valve Replacement (TAVR) during procedural planning.

The software performs computer simulation to predict post TAVR in vivo valve frame deformation of clinician selected Transcatheter Heart Valve (THV) device types and sizes.

The information provided by PrecisionTAVI is intended for use by cardiologists, radiologists, and clinical specialists, and is not intended in any way to eliminate, replace, or substitute for, in whole or in part, the healthcare provider's judgment and analysis of the patient's condition. The clinician receiving the images retains the responsibility for interpreting and validating all information and making all patient treatment decisions.

PrecisionTAVI is not intended to replace the simulated device's instructions for use for final TAVR device selection and placement.

INDICATIONS FOR USE COMPARISON

PrecisionTAVI has similar indications and the same intended use in comparison to the predicate device. The difference in indications for use is attributed to the different disease/anatomy (aortic valve vs. left atrial appendage).

TECHNOLOGICAL COMPARISON

1. Technical Method: Both the subject and predicate devices perform simulations to predict the

post-implantation device deformation by combining a predefined device model with a patient specific model of the patient anatomy.

2. Target Area: The predicate device's target area is left atrial appendage, while the subject device's target area is the aortic valve/aortic root.

3. Functionality: Both the subject and predicate device enable visualization of CT scan images (2D and 3D), generate patient specific anatomical models of aortic root (subject device) and left atrial appendage (predicate device); enable visualization of post-deployment device deformation: Transcatheter Heart Valve device (subject device) and Transcatheter Atrial Appendage Occlusion device (predicate device). The predicate device has measurement tools in addition to the functionality described above.

4. Interpretation of Images: Both the subject and predicate devices outputs are interpreted by health care professionals.

5. Modeling Strategy: Both the subject and predicate devices provide simulation outputs of the mechanical interaction between the device specific computational model and patient specific anatomical model.

6. Software Architecture: Both subject and predicate devices have DICOM data provided by clinical users as input, while the simulations results are prepared by qualified engineers/ analysts and made available with the use of web-based viewers.

7. Simulated Devices: Subject device provides simulation for the Balloon-expandable Edwards SAPIEN 3 or Ultra devices, while the predicate device provides simulation results for Boston Scientific WATCHMAN, Boston Scientific WATCHMAN FLX, and Abbott Amplatzer Amulet devices.

TESTING SUMMARY

PrecisionTAVI performance has been validated against post-TAVR CT images of 89 patients and with a registered error of $\leq \pm 2$mm for mean inflow, waist, and outflow diameter of the nominally deployed THV in $\geq 95\%$ of cases, and $\leq \pm 0.1$ for THV aspect ratio for the out-of-round deformation of the nominally deployed THV in $\geq 95\%$ of cases. More than 80% of cases have been found in agreement in both clinician and engineer qualitative assessments.

THV deployment validations were performed using data derived from clinical deployments in anatomy of 89 patients that had a tricuspid aortic valve morphology, had received a SAPIEN S3/Ultra THV (Edwards Lifesciences, Irvine, CA, USA), and had pre-TAVR as well as post-TAVR CT imaging available.

THV deformation prediction validation was performed by comparing simulated and physical/clinical device deployments. A computational model of the pre-operative aortic root geometry was reconstructed from the pre-TAVR CT image data. Then, the 3D THV model was virtually deployed into the pre-TAVR anatomy using the PrecisionTAVI software. Also, the THV geometries were reconstructed from post-operative CT image data.

Qualitative and quantitative validations were then performed by comparing the simulated THV to post-TAVR CT derived deformed THV.

The mean THV diameter at the inflow, waist and outflow regions was used to compare the agreement in predicting the THV deformation and the aspect ratio was used to evaluate agreement in predicting the out-of-round deformation of the THV.

Precision TAVI showed excellent accuracy in predicting the deployment as seen on post-TAVR CTA with 100%, 97% and 98% of all cases showing less than ± 2mm difference in THV diameter measured at the inflow, waist, and outflow regions respectively and 97%, 98% and 98% of all cases showing less than ±0.1 difference in THV aspect ratio for the out-of-round deformation between Precision TAVI simulated output and post-TAVR CTA, thus satisfying the acceptance criteria of ± 2mm for mean inflow, waist, and outflow diameter of the nominally deployed THV in ≥95% of cases, and ±0.1 for THV aspect ratio for the out-of-round deformation in ≥95% of cases.

Qualitative performance of Precision TAVI was evaluated by five (5) experienced independent clinicians in the TAVR space and three (3) trained DASI Simulations engineers. This was comprised of a side-by-side comparison of the TAVR post-procedural images (clinical outputs) with the Precision TAVI images (simulated outputs) for the (1) inflow, (2) waist, (3) outflow regions and (4) vertical cross section for each case.

Clinicians were presented with comparison image pairs spanning a range of all device sizes, age, sex, and calcium distributions and asked to respond whether they found the simulated outputs to be in close agreement with the clinical outputs. Overall, 96% of all case evaluations (48/50) were found to be in agreement with 90.5% (181/200) cut planes testing successfully, demonstrating excellent qualitative performance.

Engineers were presented with comparison image pairs spanning a range of all device sizes, age, sex, and calcium distributions and asked to respond whether they found the simulated outputs to be in close agreement with the clinical outputs. Overall, 97% and 99% of cases were found to be in agreement in eccentricity and apposition of the THV stent, thus satisfying the acceptance criteria of > 80%.

CONCLUSIONS

The characteristics that determine the functionality and performance of DASI Simulations PrecisionTAVI, the subject device, are substantially equivalent to the predicate device. The testing indicates that the subject device is as safe, as effective, and performs as well as the predicate.