



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

January 8, 2024

Re: K231324

Trade/Device Name: DASI Dimensions (V1.0)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: December 13, 2023
Received: December 14, 2023

Dear Manali Shah:

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.

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
Assistant Director
DHT8B: Division of Radiologic 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

Submission Number (if known)

K231324

Device Name

DASI Dimensions (V1.0)

Indications for Use (Describe)

DASI Dimensions is a standalone, non-invasive, clinical decision support software solution that is intended for use by cardiologists and radiologists in context of the aortic stenosis population.

DASI Dimensions provides the end-user with pre-defined images and measurements (diameters, lengths, angles, areas, and perimeters) of cardiovascular structures.

The clinician receiving the results retains the responsibility for interpreting and validating all information and making all patient treatment decisions.

DASI Dimensions is not intended to replace the clinician's decision or device's instructions for use.

DASI Dimensions is prescription use only.

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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Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	DASI Simulations
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Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	DASI Dimensions (V1.0)
Common Name	Medical image management and processing system
Classification Name	Automated Radiological Image Processing Software
Regulation Number	892.2050
Product Code	QIH

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K153736	3mensio Workstation	LLZ

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

DASI Dimensions is an image post-processing software system intended for clinical decision support in the context of pre-procedural planning of Transcatheter Aortic Valve Replacement (TAVR) procedures. The software provides users with a report of generated dimensions of cardiac structures. DASI Dimensions software is not operated by physicians.

DASI Dimensions is an off-site software system that receives cardiologists and/or radiologists' input via upload of patient multiphase DICOM computed tomography angiography (CTA) chest image files through DASI Simulations web portal. The processed report is then available for viewing and downloading. The report is generated using proprietary algorithms that (a) detect key aortic root control points with the assistance of a static deep learning artificial intelligence (AI) model and (b) calculate anatomical measurements relevant for pre-TAVR evaluation. DASI Simulations engineers perform quality checks at both steps before releasing the report to the end user via the portal.

DASI Dimensions does not come in contact with the patient, nor does it control any life sustaining devices. The information provided by DASI Dimensions is not diagnostic, nor does it determine recommended medical care.

The cardiologists and/or radiologists receiving the results retains the responsibility for interpreting and validating all information and making all patient treatment decisions.

DASI Dimensions:

- Supports quantification of cardiac structures for pre-procedural planning of aortic stenosis patients in consideration for potential TAVR procedures.
- Provides the measurement of different structures of the heart, e.g., aorta, aortic root, aortic valve.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

DASI Dimensions is a standalone, non-invasive, clinical decision support software solution that is intended for use by cardiologists and radiologists in context of the aortic stenosis population.

DASI Dimensions provides the end-user with pre-defined images and measurements (diameters, lengths, angles, areas, and perimeters) of cardiovascular structures.

The clinician receiving the results retains the responsibility for interpreting and validating all information and making all patient treatment decisions.

DASI Dimensions is not intended to replace the clinician's decision or device's instructions for use.

DASI Dimensions is prescription use only.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

DASI Dimensions and the predicate device have similar indications for use and have the same intended use. Both devices provide the end-user with reports for pre-operative planning for cardiovascular interventions with images and measurements. The difference in the two indications is the support of certain modules (dimensions in coronary arteries, quantification of calcifications and certain visualization techniques such as volume rendering, MPR etc.) by the predicate device that are not supported by DASI Dimensions.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

A comparison of the technological characteristics of the subject device to the predicate device is presented below:

1. Target Area: The predicate device's target areas include the heart, ascending, descending aorta and peripheral vasculature. The subject device's target areas are cardiac structures specific to Transcatheter Aortic Valve Replacement such as aortic root, aortic valve, sinus of valsalva, sinotubular junction and ascending aorta.
2. Functionality: Both the subject and predicate device enable linear (diameter/perimeter), angular and areal measurements of cardiac structures with annotations. The predicate device has additional tools for volume measurements and scoring of calcification in addition to the functionality described above.
3. Interpretation of Images: The outputs of both the subject and predicate devices are interpreted by Health Care Professionals (HCP).
4. Technical Method: Both the subject and predicate devices use an automated algorithm involving segmentation and centerline detection of cardiac structures.
5. Software Architecture: Both the subject and predicate devices have multiphase DICOM data provided by clinical users as input, while the reports are prepared by qualified operators and made available digitally.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Non-clinical bench performance testing includes the relevant information described in the FDA guidance document "Recommended Content and Format of Non-Clinical Bench performance Testing Information in Premarket Submissions". The subject device has been evaluated and verified in accordance with software predefined specifications and applicable performance standards through software verification and validation testing.

Software verification and validation testing confirmed that the software requirements fulfilled the predefined acceptance criteria. The reference standard was derived from 2 qualified truthers truthing each CTA, whose measurements were averaged for each case. If there

was a significant variance between the initial two truthers, an adjudicator was involved. To ensure the uniqueness of all data used in the studies, each case UID (unique identifier) was monitored. Relevant studies incorporated data with various distributions of ethnicity, gender, and age. All data was collected through the DASI Simulations secure server, AWS, through internal workstations operated by trained DASI Dimensions operators.

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

As described in the DASI Dimensions Software Verification and Validation Plan (TP131), the following testing was completed:

(i) Software Verification and Validation: Software verification activities were done to verify that design inputs described in the software requirements specifications can be traced to design outputs including corresponding software design documents, test procedures, and system software. Software validation activities were performed to ensure that the design outputs meet design inputs using a complete DASI Dimensions system software release.

a. Traceability Matrix (RMF112): Generated to trace each functional requirement (design input) through implementation (design output). Functional Requirements testing (TR142 and TR143) were performed to ensure that each design input can be traced to the design output. The results showed successful performance of the functional testing.

b. AI Control Point Detection Validation Study (WI112 and TR132) trained and tested the AI model using training, validation, and testing datasets. Control point deviation has been shown to have clinically significant impact on the final outputs when > 3 mm of error is introduced thus an acceptance criteria of ≤ 3 mm was used to determine success of an individual control point. In the AI testing dataset the AI generated control points were compared to manual control points generated by qualified DASI Dimensions operators (ground truth), error resulted in a success rate of 75.3% of points. All testing, validation, and training cases were independent of each other and were not used in any other validation studies.

c. Automatic Measurements Validation Study (TP133 and TR133) was performed to verify the accuracy of the automatic measurement process of DASI Dimensions. The automatic measurement outputs generated using control points were compared to the measurements generated manually by clinicians using current standard of care methods. The primary measurements showed $\leq 15\%$ error in $\leq 95\%$ of cases thus satisfying the acceptance criteria. The secondary measurements showed $\leq 20\%$ error in $\leq 95\%$ of the cases thus satisfying the acceptance criteria. The automatic measurement outputs showed agreement with the manual measurements generated by clinicians with no statistically significant differences between the two measurement groups.

d. Performance Validation Study (TP134 and TR134) was used as validation of the overall performance of the device. A cohort of patient CT images ($n=40$), representative of the general population of patients with tricuspid aortic valves and aortic stenosis, were processed through the DASI Dimensions semi-automatic AI enhanced workflow by trained DASI Simulations operators where outputs were compared to qualified clinician truther generated measurements. The AI generated control points performed at an 85.3% success rate achieving the acceptance criteria of $\geq 75\%$. The mean percentage error in primary outputs was 0.93% (CI: positive 8.65%, negative -6.80%) and -1.02% (CI: positive 3.49%, negative -5.54%) respectively for the annulus area and perimeter, satisfying the acceptance criteria of $\leq 10\%$ error in $\geq 95\%$ of cases. The mean percentage difference in secondary outputs was 4.77% (CI: positive 11.26%, negative -1.72%), 4.13% (CI: positive 11.61%, negative -3.35%), 3.29% (CI: 8.83%, negative -2.25%) respectively for the left-, right- and non-coronary sinus of valsalva diameters, 1.25% (CI: positive 8.80%, negative -6.30%) and 2.20% (CI: positive 8.46%, negative -4.06%) respectively for sinotubular junction maximum and minimum diameters, and 0.12% (CI: positive 5.29%, negative -5.05%) for the ascending aorta maximum diameter, satisfying the acceptance criteria of $\leq 15\%$ error in $\geq 95\%$ of cases. The mean percentage difference in the tertiary output between DASI Dimensions and clinician truthing was 2.66% (CI: positive 24.98%, negative -19.66%) for the aortic valve angle, satisfying the acceptance criteria of $\leq 25\%$ error in $\geq 95\%$ of cases. No trends were observed between the aortic valve annulus error and patient or scan characteristics. Scans were independent of those used for AI training or any other validation study.

e. Operator Variability Study (TP136 and TR136) validated the repeatability and reproducibility of DASI Dimensions outputs produced by different operators. The study evaluated whether the observed inter-operator variability in the selection of control points and alteration of measurement location/contours can introduce significant difference in the DASI Dimensions measurement outputs. Using a dataset of CTAs ($n = 14$), comparison of the annulus area outputs from DASI Dimensions made by trained DASI Simulations operators ($n = 5$) showed excellent inter-operator agreement (precision) and to clinician ground truth measurements (accuracy), with an ICC of 0.96 and $\leq 10\%$ difference from clinician measurements in $\geq 95\%$ of cases. Both acceptance criteria were met, thus demonstrating that the variability in DASI Dimensions outputs due to operator inputs is within acceptable limits.

f. Human Factors/Usability Validation (TP137 and TR137) was conducted to assess the DASI Dimensions operator ($n = 6$) interactions with the Processing Stage of DASI Dimensions software system user interface to identify use errors that would or could result in serious harm to the patient or user. The purpose of the Human Factors and Usability Testing is to assess the effectiveness of risk management measures. Overall, the DASI Dimensions Processing Stage Human Factors evaluation showed that the DASI Dimensions Processing Stage user interface is user-friendly and reduces use-related risk. There were no instances of a system failure where a failure is defined as the inability for a participant to complete any of the critical tasks provided to them. The findings of the DASI Dimensions Processing Stage Human Factors evaluation shows that the relevant hazards have been reduced to a residual risk that is acceptable. The

100% success rate of the system and positive feedback regarding how intuitive the user interface was showed that the "Operational Hazard Use Error" (Hazard ID Section 9.0) and "Information Hazard - Labeling" (Hazard ID Section 10.0) hazards were successfully reduced to an acceptable residual risk due to a remote probability of ever occurring.

g. Control Point Sensitivity Study (TP140 and TR140) focused on assessing the sensitivity of the DASI Dimensions automatic measurement outputs to the error in the aortic control points coordinates. Using a dataset of CTAs (n = 14), measurements were generated using control points that were iteratively perturbed in designated directions and magnitudes and were compared with the baseline measurements which were generated using an unperturbed set of verified control points. At both 1.5 mm and 3.0mm perturbations of the control points, the resulting automatic annulus area measurements had percent errors $\leq 10\%$, meeting the acceptance criteria.

(ii) Cybersecurity testing (TP130 and TR130) was conducted to ensure that there were no unidentified vulnerabilities and that the appropriate risk control measures were implemented to protect from known vulnerabilities when the device is subject to a source of threat. The testing showed that appropriate risk control measures were implemented.

The non-clinical verification and validation test results established that the device meets the design requirements and intended use. During the development, potential hazards were evaluated and controlled through risk management activities. The performance testing demonstrates that the device meets all its specifications.

No prospective clinical trials were conducted in support of this Traditional 510(k).
Clinical evaluation, as a set of ongoing activities conducted in the assessment and analysis of DASI Dimensions clinical safety, effectiveness and performance, are outlined in non-clinical testing summary.

The subject device has been evaluated and verified in accordance with predefined software specifications and applicable performance standards through software verification and validation testing. The non-clinical verification and validation test results established that the device meets its design requirements and intended use. During the development, potential hazards were evaluated and controlled through risk management activities. The performance testing demonstrates that the device meets all its specifications. The data generated from each test also supports a finding of substantial equivalence based on meeting testing requirements, special controls, and consensus standards.

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