



March 16, 2026

Voronoi Health Analytics Incorporated
Mirza Faisal Beg
Director and Chief Executive/Scientific Advisor
#250-997 Seymour St.
Vancouver, British Columbia V6B 3M1
Canada

Re: K253944

Trade/Device Name: Data Analysis Facilitation Suite (DAFS)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: February 18, 2026
Received: February 19, 2026

Dear Mirza Faisal Beg:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

A handwritten signature in black ink that reads "Jessica Lamb". The signature is written in a cursive style. In the background, there is a large, light blue watermark of the letters "FDA".

Jessica Lamb, PhD
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

Indications for Use

Submission Number (if known)

K253944

Device Name

Data Analysis Facilitation Suite (DAFS)

Indications for Use (Describe)

DAFS is a software-only medical device intended for use by trained healthcare professionals for the automated segmentation, visualization, and quantitative analysis of anatomical structures in computed tomography (CT) images.

The software processes DICOM Part 10 formatted CT image data to identify, segment anatomical structures, including body composition tissues and internal organs and annotate DICOM slices by anatomical landmarks. The device provides quantitative measurements of these structures, including area, volume, and intensity values, and displays 2D and 3D visual representations.

The software provides tools for visualization, review, and manual editing of segmentation and slice annotation results and associated measurements.

DAFS is intended for use as an adjunct to clinical assessment. The device does not provide diagnostic interpretation, and all results must be reviewed and confirmed by a qualified healthcare professional.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Contact Details

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

Applicant Name	Voronoï Health Analytics Incorporated
----------------	---------------------------------------

Applicant Address	#250-997 Seymour Street Vancouver BC V6B 3M1 Canada
-------------------	---

Applicant Contact Telephone	1-604-999-8783
-----------------------------	----------------

Applicant Contact	Dr. Mirza Faisal Beg
-------------------	----------------------

Applicant Contact Email	mfbeg@voronoïhealthanalytics.com
-------------------------	----------------------------------

Device Name

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

Device Trade Name	Data Analysis Facilitation Suite (DAFS)
-------------------	---

Common Name	Medical image management and processing system
-------------	--

Classification Name	Automated Radiological Image Processing Software
---------------------	--

Regulation Number	892.2050
-------------------	----------

Product Code(s)	QIH
-----------------	-----

Legally Marketed Predicate Devices

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

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K223556	DeepCatch	QIH

Device Description Summary

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

Data Analysis Facilitation Suite (DAFS) is an image processing software-only medical device that provides automatic tissue segmentation, labeling, visualization, and quantitative characterization of CT images for specific target body tissues. Data output includes quantification of volume, cross-sectional area and intensity for body composition tissues and internal organs.

Intended Use/Indications for Use

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

DAFS is a software-only medical device intended for use by trained healthcare professionals for the automated segmentation, visualization, and quantitative analysis of anatomical structures in computed tomography (CT) images.

The software processes DICOM Part 10 formatted CT image data to identify, segment anatomical structures, including body composition tissues and internal organs and annotate DICOM slices by anatomical landmarks. The device provides quantitative measurements of these structures, including area, volume, and intensity values, and displays 2D and 3D visual representations.

The software provides tools for visualization, review, and manual editing of segmentation and slice annotation results and associated measurements.

DAFS is intended for use as an adjunct to clinical assessment. The device does not provide diagnostic interpretation, and all results must be reviewed and confirmed by a qualified healthcare professional.

Indications for Use Comparison

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

The indications for use of the predicate device are equivalent to the DAFS device in this submission.

The proposed device, DAFS, has the same technological characteristics as the predicate device, DeepCatch.

Indications for use: Essentially equivalent

Type of use: Both are Prescription Use

User population: Both are Clinical Experts

Imaging Modalities: Both are DICOM imaging information from CT

Feature/Functionality: Both are: Analysis and Measurement, 2D/3D visualization, Segmentation, 3D rendering, Export of CSV data

Segmentation Regions: Both devices segment similar regions

Visualization/Edit Tools: Both devices offer equivalent functionality and tools

Data reporting: Both devices provide data reporting

Export file formats: Both devices offer tabular and PDF graphical export file formats

Non-Clinical and/or Clinical Tests Summary & Conclusions

The performance of the DAFS artificial intelligence (AI) algorithms was evaluated using an independent internal testing dataset derived from multi-institutional CT studies curated by The Cancer Imaging Archive (TCIA).

The independent validation dataset consisted of CT scans from 124 adult subjects not used during algorithm training. Subject-level separation between training and testing datasets was ensured by verifying unique PatientID, SeriesInstanceUID and AcquisitionNumber DICOM identifiers.

The internal testing consisted of 60 females (48.4%) and 64 males (51.6%). The age distribution included 4.8% of subjects under 40 years, 37.1% between 40–59 years, 53.2% between 60–79 years, and 4.8% aged 80 years or older. The majority of cases (90.3%) were between 40 and 79 years of age, representing the primary adult CT imaging population. These datasets originated primarily from U.S.-based clinical research studies supported by the National Cancer Institute. Race and/or ethnicity metadata were available for 78 subjects (62.9%) of the testing dataset, while the remaining 46 scans did not include race or ethnicity information in the source datasets. Among the cases with available metadata, the reported categories included White (n=54), Hispanic or Latino (n=9), Black (n=6), Not Hispanic or Latino (n=6), and Asian (n=3). Race and ethnicity metadata were reported according to the conventions used by the original source datasets.

The test dataset included CT scans acquired on systems from Siemens, GE Medical Systems, Philips, Toshiba and United Imaging Healthcare consisting of more than ten unique scanner models. Slice thickness varied as follows: ≤ 1.0 mm: (15.3%), 1.25–2.5 mm: (25.8%) and 2.5 mm: (58.9%). Both contrast enhanced and non-contrast CT were included.

Disease information was available for 121 of 124 CT scans (97.6%) in the independent testing dataset. Cases included a range of malignant and non-malignant conditions. The largest disease categories were lung cancer (n=34), genitourinary cancers including kidney, prostate, and bladder (n=23), gastrointestinal/colorectal cancers (n=18), other primary cancers (n=17), and gynecological cancers (n=14). A total of 15 scans represented non-malignant or indeterminate findings, including healthy cases and benign or indeterminate nodules or polyps. Three scans had unavailable disease metadata.

Reference standard annotations were generated through manual segmentation and vertebral landmark annotation performed by trained anatomy specialists using standardized anatomical protocols. All annotations underwent a structured quality assurance process that included co-rater review and approval by experienced anatomy team leads, followed by final review by a board-certified Nuclear Medicine physician to ensure anatomical accuracy and consistency. These expert-reviewed annotations served as the ground truth reference standard for evaluation of the automated vertebral annotation and tissue segmentation algorithms.

The performance of the DAFS algorithms was evaluated by comparing automated outputs against expert-generated reference standard annotations. Vertebral annotation accuracy was assessed by measuring slice-level positional differences between automated landmarks and the reference standard. Results demonstrated a median slice error of 0 slices across vertebral levels, with the majority of annotations within one slice of the reference standard. Segmentation performance was evaluated using the Dice Similarity Coefficient (DSC) across the anatomical structures supported by the device. Overall, the algorithms demonstrated high agreement with the reference standard, with most major anatomical structures achieving mean Dice scores greater than 0.90.

The DAFS algorithms were developed using a collection of multi-institutional CT imaging datasets representing a range of anatomical presentations, imaging protocols, scanner manufacturers, and fields of view. The training data included CT studies acquired for a variety of clinical indications and imaging conditions to support algorithm generalizability.

DAFS is designed as a human-in-the-loop system. All generated segmentations and vertebral annotations are required to be reviewed and, if necessary, adjusted by a qualified healthcare professional prior to clinical use.