



October 20, 2025

Avatar Medical
Adeline Francois
VP QARA and Clinical Affairs
11 rue de Lourmel
Paris, 75015
France

Re: K252665
Trade/Device Name: brAIn™ Shoulder Positioning
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: August 22, 2025
Received: August 25, 2025

Dear Adeline Francois:

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
Assistant Director
Imaging Software Team
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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K243292

?

Please provide the device trade name(s).

?

brAln™ Shoulder Positioning

Please provide your Indications for Use below.

?

brAln™ Shoulder Positioning is intended to be used as an information tool to assist in the preoperative surgical planning and visualization of a primary total shoulder replacement.

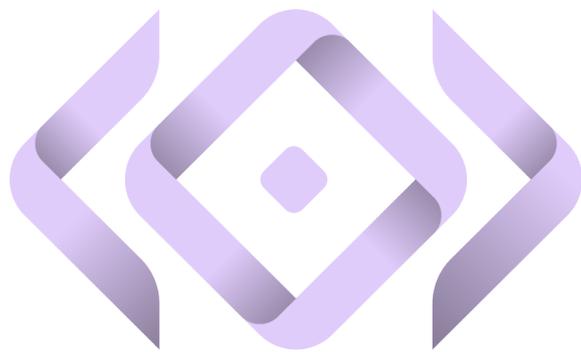
Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)
 Over-The-Counter Use (21 CFR 801 Subpart C)

?

K252665

510(k) Summary



AVATAR MEDICAL

- Device Name: brAI[™] Shoulder Positioning
- 2.1 Submission correspondent
- 2.2 Subject Device
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- 2.9 Statement of Substantial Equivalence

Device Name: brAI[™] Shoulder Positioning

2.1 Submission correspondent

Table 2A – Submission correspondent

510(k) Sponsor	Avatar Medical
Address	11 rue de Lourmel 75015 Paris France
Correspondence Person	FRANCOIS Adeline VP QARA and Clinical Affairs
Contact Information	Email: adeline@avatarmedical.ai
510(k) number	K252665
510(k) Summary Date	Aug 22, 2025

2.2 Subject Device

Table 2B – Subject Device

Trade Name	brAI [™] Shoulder Positioning
Common Name	Planning Software for Total Shoulder Arthroplasty
Classification Name	System, Image Processing, Radiological

Regulation Number	21 CFR 892.2050
Regulation Name	Medical Image Management and Processing System
Product Code:	QIH, automated radiological image processing software
Subsequent Product Code:	LLZ, system, image processing, radiological
Regulatory Class	II
Classification Panel	Radiology

2.3 Predicate Device

Table 2C – Predicate Device

Trade name	FX SPS
Common Name	Planning software for Total Shoulder Arthroplasty
Premarket Notification	K213922
Classification Name	System, Image Processing, Radiological
Regulation Number	21 CFR 892.2050
Regulation Name	Medical Image Management and Processing System
Product Code	LLZ
Regulatory Class	II
Classification Panel	Radiology

2.4 Device Description

The brAln™ Shoulder Positioning software is a cloud-based application intended for shoulder surgeons. The software does not perform surgical planning but provides tools to assist the surgeon with planning primary anatomic and reverse total shoulder replacement surgeries using FX Shoulder Solutions implants. The software is accessible via a web-based interface, where the user is prompted to upload their patient's shoulder CT-scan (DICOM series) accompanied with their information in a dedicated interface. The software automatically segments (using machine learning) and performs measurements on the scapula and humerus anatomy contained in the DICOM series. These segmentations serve as a foundation for the surgeon's manual planning, which is performed using an interactive 3D viewer that allows for soft tissue visualization. The surgeon positions the glenoid and humerus implants manually within this same 3D interface using a dedicated manipulation panel. The changes in shoulder anatomy resultant from the implants are relayed in a post-position interface that displays information related to distalization and lateralization. The software outputs a planning multimodal summary that includes textual information (patient information, pre- and post-op measurements) and visual information (screen captures of the shoulder pre- and post-implantation).

2.5 Indications for Use Statement

brAln™ Shoulder Positioning is intended to be used as an information tool to assist in the preoperative surgical planning and visualization of a primary total shoulder replacement.

2.6 Substantial Equivalence Discussion

The following table compares brAln™ Shoulder Positioning to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table 2D: Comparison of Characteristics

Feature/ Function	Predicate Device: FX SPS (K213922)	Subject Device: brAln™ Shoulder Positioning
Intended Users	Healthcare Professionals	Healthcare Professionals
Intended Environment	Healthcare facilities such as hospitals and clinics	Healthcare facilities such as hospitals and clinics
Device Class	Class II	Class II
Type of software	Web-based software	Web-based software
Use time	Pre-operatively	Pre-operatively
Imaging used	CT-scan images	CT-scan images
Type of implants planned	Anatomical and reverse shoulder implants	Anatomical and reverse shoulder implants
Manual/Automatic segmentation	Manual segmentation performed.	Automatic segmentation performed.
User profiles	User profiles define the authorized actions for the user.	User profiles define the authorized actions for the user.
Case management	List of cases	List of cases
Tools	Milling tool	Milling tool (called reaming)
Patient Information Display	<ul style="list-style-type: none"> • Patient last name • Patient first name • Patient sex • Patient birthdate • Shoulder side • Surgery date 	<ul style="list-style-type: none"> • Patient last name • Patient first name • Patient sex • Patient birthdate • Patient age • Patient height • Patient weight

Feature/ Function	Predicate Device: FX SPS (K213922)	Subject Device: brAln™ Shoulder Positioning
		<ul style="list-style-type: none"> • Shoulder side • Surgery date
Bone representation	3D and 2D representation of the humerus and the scapula	3D and 2D representation of the humerus and the scapula.
2D DICOM Viewer	2D DICOM view Axial views are displayed in 2D DICOM Viewer interfaces.	The 2D DICOM Viewer Interface displays 2D DICOM images Axial and coronal views are displayed in two separate 2D DICOM Viewer interfaces.
3D Viewer	3D reconstruction in an interactive viewing interface	3D reconstruction in an interactive viewing interface with soft tissues (Pre-Position Interface only)
Planning step	<ul style="list-style-type: none"> • Case details, • Segmentation, • Glenoid • Planning Report 	<ul style="list-style-type: none"> • Create plan, • Validate Segmentations, • Pre-position with the validation of Shoulder Landmarks, • Implant, • Glenoid/humerus, • Post position, • Surgical planning Report
Landmarks / Measurements	<ul style="list-style-type: none"> • Manual Landmarks/Measurements performed: Shoulder Measurements, scapula neck length, posterior subluxation, glenoid reaming depth. • Manual measurements performed: Feature that displays and calculates the distance between two points. 	<ul style="list-style-type: none"> • Pre-positioning or Semi-automatic Landmarks/Measurements performed: Shoulder Measurements, backside seating, 3D subluxation, glenoid reaming depth. • Manual measurements performed (Ruler Tool): Feature that displays and calculates the distance between two points.
Implant Initial Placement	Manual initial placement performed.	Pre-positioning or Semi-automatic initial placement performed.
Planning report	Planning report comprising patient information, implant and measurements name, its preoperative value, and the planned value. It also comprises images from the preoperative situation with different camera angles, image showing the drilling simulation pin, images showing the scapula and the Glenoid implant.	Planning report comprising patient information, implant and measurements name, its value in pre-position, and the value in post-position. It also comprises images from the Pre-Position tab with different camera angles, images showing the K-Wire placement, images showing the

Feature/ Function	Predicate Device: FX SPS (K213922)	Subject Device: brAln™ Shoulder Positioning
		Glenoid implant, and images from the Post-Position Interface showing both the scapula and humerus and the chosen implant components.
Recommendations	Does not include any predictions and recommendations.	Does not include any predictions and recommendations.

The performance of brAln™ Shoulder Positioning was validated by nonclinical tests. All verification testing met the acceptance criteria (passed), demonstrating that the software fulfills its requirement specifications.

2.7 Predicate Device Comparison

The subject device and the primary device have similar indications for use in that they are both intended to use CT-scan imaging and the intended type of implants and duration of use are also similar.

The **brAln™ Shoulder Positioning** has minor differences from the predicate device.

Internal verification and validation testing confirms that product specifications are met which are equivalent in design and technological characteristics to the predicate device. The testing results confirm that the software validation requirements have been successfully met, supporting the acceptance of the device.

brAln™ Shoulder Positioning passed all testing and supports the claims of substantial equivalence to the predicate device.

Overall, these differences do not raise new questions of safety or effectiveness and therefore the subject device is substantially equivalent to the predicate device.

2.8 Performance Data

Software Verification and Validation Tests:

Safety and performance of the brAln™ Shoulder Positioning has been evaluated and verified in accordance with software specifications and applicable performance standards through software verification and validation testing. The model was evaluated taking into account applicable requirements of the FD&C Act and 2081 implementing regulations.

Additionally, the software validation activities were performed in accordance with *ANSI AAMI IEC 62304:2006/A1:2016 - Medical device software – Software life cycle processes*, in addition to the FDA Guidance documents, *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"* and *"Content of Premarket Submission for Management of Cybersecurity in Medical Devices."*

Segmentation Performance Testing:

The brAln™ system's automatic segmentation was validated against manual segmentation, meeting a mean Dice Similarity Coefficient (DSC) on the testing set greater than or equal to 0.95. All tests confirmed that the segmentation performance meets the acceptance criteria, ensuring compliance.

The automatic segmentation provided by brAln™ Shoulder Positioning was validated against manual segmentation performed. The validation criterion was a Dice Similarity Coefficient (DSC) coefficient of 0.95 or higher, demonstrating that the segmentation produced by the model after post-processing closely matches the ground truth.

The dataset is comprised of 508 pairs of 3D images (DICOM series) together with their segmentation labels. The 3D images have on average 467 (axial) slices of resolution 512x512 pixels.

The dataset is divided into two partitions:

- **Training Set** (65.9%, 335 samples)
 - **Shoulder Side:** 43.3% left (145), 56.7% right (190)
 - **Gender:** 57.9% female (84), 41.4% male (60), 0.7% unspecified (1) for left; 57.4% female (109), 42.1% male (80), 0.5% unspecified (1) for right
 - **Geographical Origin:** 46.9% Europe (68), 56.4% USA (77) for left; 52.6% Europe (100), 47.4% USA (90) for right
- **Testing Set** (34.1%, 173 samples)
 - **Shoulder Side:** 45.7% left (79), 54.4% right (94)
 - **Gender:** 55.7% female (44), 44.3% male (35) for left; 63.8% female (60), 36.2% male (34) for right
 - **Geographical Origin:** 58.2% Europe (46), 41.8% USA (33) for left; 56.4% Europe (53), 43.6% USA (41) for right

The data corresponds to patients that underwent a total shoulder arthroplasty with an FX Shoulder implant without any further specific selection, representing a diversity in shoulder side, patient gender, imaging equipment, institutions, study year and geographical provenance. The protocol used for image acquisition is standard for patient undergoing a total shoulder arthroplasty.

The labels were created manually by medical professionals.

To prevent any form of data leakage, we took the following precautions: first, the training and testing datasets were split at the patient level to ensure that no patient data was included in both sets. Second, to ensure both a representative split of the dataset, we performed a stratified split based on patient gender, shoulder side and geographical region of origin. With this approach, we ensure that both sets accurately reflect the intended patient population. Besides, we decided to boost the representation of study collected in 2024 in the testing dataset compared to the training dataset, enabling thus a better generalization on future images and increased independence between datasets.

Shoulder Side Detection performance testing:

Validation compared the correct shoulder side (right or left) in DICOM images to a manual assessment performed by a Clinical Solutions Specialist. All performance tests for Shoudler Side Detection validation were successfully completed with no deviations, confirming compliance with the required performance standards.

Measurement Accuracy performance testing:

Validation compared the accuracy of the brAln™ Shoulder Positioning software measurement when editing the position of landmarks/implants within the software to the reported accuracy of the predicate. All performance tests for Measurement Accuracy Validation were successfully completed with no deviations, confirming compliance with the required performance standards.

The acceptance criterion for the Measurement Accuracy Performance Validation Protocol is set at 1° for angle measurement, 1 mm for distance measurement and 1% for 3D subluxation when updating the position of landmarks and implants.

Landmark Performance Testing:

Validation compared pre-positioning with final positions adjusted by experts, achieving accuracy similar to manual positioning with a 3 mm mean distance as the acceptance criterion. All performance tests for landmark validation were successfully completed with no deviations, confirming compliance with the required performance standards.

Streaming Stability Testing:

Validation demonstrated that the system can handle simultaneous usage by multiple users without performance degradation regarding the following metrics: frames per seconds, jitter and packet loss. All performance tests for the streaming stability were successfully completed with no deviations, confirming compliance with the required performance standards.

Ruler Performance Testing:

Validation assessed the measurement precision of the brAln™ Shoulder Positioning software's ruler tool by comparing its accuracy between anatomical landmarks to theoretical distances calculated from their spatial coordinates. The tool is expected to display the linear (Euclidean) distance between two user-selected points on the scapula's unreamed 3D mesh, with a precision of one millimeter. All performance tests for the ruler tool accuracy were successfully completed with no deviations, confirming compliance with the required performance standards.

2.9 Statement of Substantial Equivalence

The brAln™ Shoulder Positioning is as safe and effective as the predicate device. The brAln™ Shoulder Positioning has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device.

The minor technological differences between the brAln™ Shoulder Positioning and its predicate device raise no new issues of safety or effectiveness. The performance data demonstrates that the brAln™ Shoulder Positioning is as safe and effective as the predicate device.

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise additional questions regarding its safety and effectiveness as compared to the predicate device.

brAln™ Shoulder Positioning, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.