



May 21, 2026

Smart Alfa Teknoloji San. Ve Tic. A.S.
Utku Kaya
Chief Executive Officer
Universiteler Mah. Ihsan Dogramaci Blv. No:17-1 #109
Cankaya
Ankara, 06800
Turkey

Re: K260234

Trade/Device Name: MSK Go
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: May 6, 2026
Received: May 6, 2026

Dear Utku Kaya:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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.

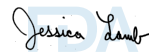
All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (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 blue ink that reads "Jessica Lamb". The signature is written in a cursive style.

Jessica Lamb, Ph.D.

Assistant Director

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

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

K260234

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Please provide the device trade name(s).

?

MSK Go

Please provide your Indications for Use below.

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MSK Go is indicated to assist healthcare professionals trained and qualified in MSK (musculoskeletal) ultrasound by highlighting anatomical structures on musculoskeletal ultrasound images acquired using the compatible ultrasound systems. MSK Go is indicated for use in adult patients 18 years of age or older.

MSK Go is not intended for diagnostic purposes, or to replace clinical decision-making.

The following joint regions are supported: Shoulder, Elbow, Hand and Wrist, Knee, Foot and Ankle

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

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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510(k) Summary

Applicant Details

Name: Smart Alfa Teknoloji San. Ve Tic. A.Ş.
Address: Universiteler Mah. Ihsan Dogramaci Blv.
No:17/1-109, 06800 Ankara, Türkiye
Contact Name: Utku KAYA
utku.kaya@smartalpha.ai
Date Prepared : January 19, 2026

Device Details

Device Trade Name : MSK Go
Common Name : Automated Radiological Image Processing Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management and Processing System
Regulatory Class : Class II
Product Code : QIH

Predicate Device Details

Device Trade Name: Clarius AI (K222406)
Common Name : Automated Radiological Image Processing Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management and Processing System
Regulatory Class : Class II
Product code: QIH

Device Description

MSK Go is a software as a medical device (SaMD) designed to assist healthcare professionals in the visualization and identification of musculoskeletal (MSK) anatomy in ultrasound images by highlighting anatomical structures.

MSK Go operates within compatible diagnostic ultrasound systems and receives the ultrasound image stream from the host system. It provides assistive visual feedback to the ultrasound operator through the ultrasound system user interface in the form of anatomical name labels, color overlays and a detection indicator that reflects the detection completeness level of supported anatomical structures for the current image.



While it enhances anatomy visualization, it does not guide image acquisition or provide any diagnostic decision replacing the clinician's expertise.

MSK Go is compatible with GE HealthCare Venue Go™ and Venue Sprint™ ultrasound systems (K251322).

Indications for Use

MSK Go is indicated to assist healthcare professionals trained and qualified in MSK (musculoskeletal) ultrasound by highlighting anatomical structures on MSK ultrasound images acquired using the compatible ultrasound systems. MSK Go is indicated for use in adult patients 18 years of age or older.

MSK Go is not intended for diagnostic purposes, or to replace clinical decision-making.

MSK Go is for use in the following joints:

- Shoulder
- Elbow
- Wrist and Hand
- Knee
- Ankle and Foot

Substantial Equivalence

The following table presents a comparison of the subject device, MSK Go, with the predicate device, Clarius AI. The comparison shows that MSK Go has similar indications for use, employs a comparable AI-enabled image processing approach, and provides automated musculoskeletal ultrasound image processing through anatomical structure detection and segmentation, consistent with the legally marketed predicate device.

	Subject Device	Predicate Device	Comments
	MSK Go	Clarius AI (K222406)	
Manufacturer	Smart Alfa Teknoloji San. ve Tic. A.Ş.	Clarius Mobile Health Corp.	-
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	Same

Regulatory Class	Class II	Class II	Same
Product Code	QIH	QIH	Same
Regulation Name	Medical Image Management and Processing System	Medical Image Management and Processing System	Same
Device Classification Name	Automated Radiological Image Processing Software	Automated Radiological Image Processing Software	Same
Rx/OTC	Rx	Rx	Same
Operational Mode	Not to be used as a diagnostic device	Not to be used as a diagnostic device	Same
Intended use	Non-invasive processing of ultrasound images using automatic image segmentation of anatomical structures utilizing artificial intelligence algorithms.	Non-invasive processing of ultrasound images using automatic image segmentation and measurement of anatomical structures utilizing artificial intelligence algorithms.	The predicate device provides an additional function for caliper placement on the segmentation, while the subject device does not. The subject device supports a broader range of anatomical structures and provides a detection indicator that reflects detection completeness of supported anatomical structures.
Indications for use	MSK Go is intended for use by trained healthcare professionals to automatically identify and segment anatomy on ultrasound data acquired by compatible ultrasound systems.	Clarius AI is intended for use by trained healthcare professionals to semi automatically place calipers for non-invasive anatomical measurements on ultrasound data acquired by the Clarius Ultrasound Scanner.	Both devices are intended for processing ultrasound images for anatomy segmentation. Predicate device provides caliper placement on the segmentation while the subject device only highlights.

Anatomical Site	Multiple structures in multiple views of Shoulder, Elbow, Hand/Wrist, Knee, Foot/Ankle	Single structure in single views of Knee, Foot/Ankle	The subject device supports a broader range of joints, including multiple views and musculoskeletal structures.
Intended Use Environment	Healthcare setting	Healthcare setting	Same
Intended users	Healthcare professionals who are trained and qualified in MSK (musculoskeletal) ultrasound.	Licensed healthcare professionals who are trained and qualified in MSK (musculoskeletal) ultrasound.	Same
Target Population	Patients 18 years of age or older.	Patients 18 years of age or older.	Same
Device hardware	Software integrated into compatible ultrasound system's software.	Software integrated into compatible ultrasound system's software.	Same
Input	MSK ultrasound images	MSK ultrasound images	Same
Output	MSK ultrasound images with highlighted anatomy and a detection indicator.	MSK ultrasound images with highlighted anatomy and automatic placement of measurement calipers for anatomical structures (tendons)	Similar; the subject device also displays a detection indicator that reflects the detection completeness of anatomical structures. Additionally, the predicate device provides caliper placement on the highlighted structures.
Imaging Modality	Ultrasound	Ultrasound	Same
Image source	Compatible ultrasound systems through a programming interface	Compatible ultrasound systems through a programming interface	Same

Software device that operates on off-the-shelf hardware	Yes	Yes	Same
Device uses AI/ML algorithms	Yes	Yes	Same
Algorithm type	Locked deep learning models	Locked deep learning models	Same

Summary of Non-Clinical Performance Testing

MSK Go was designed and developed in accordance with applicable requirements, design controls, and standards to establish safety and effectiveness of the device.

Non-clinical performance testing has demonstrated that MSK Go complies with the following FDA-recognized consensus standards:

Standard Recognition Number	Title of Standard
13-79	IEC 62304:2006 + A1:2015 – Medical device software — Software life cycle processes
5-40	ISO 14971:2019 – Medical devices — Application of risk management to medical devices
5-114	IEC 62366-1:2015 + A1:2020 – Medical devices — Part 1: Application of usability engineering to medical devices
5-117	ISO 15223-1:2016 – Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied

Safety and performance of MSK Go has been evaluated through verification and validation testing in accordance with software specifications and applicable performance standards. Traceability between requirements, design specifications, risks, and verification testing of the subject device was established and maintained. All

software requirements and risk analysis have been successfully verified and traced. Software verification and validation activities were conducted per IEC 62304:2006 + AMD1:2015 and ISO 14971:2019, and in accordance with applicable FDA guidance documents. A comprehensive risk analysis was performed and appropriate risk controls were implemented to mitigate identified hazards. Applicable software documentation for a Moderate Level of Concern software has been provided.

Cybersecurity control design and testing were performed in accordance with FDA cybersecurity guidance for medical device software, addressing prevention of unauthorized access, modification, misuse, and denial of use. Cybersecurity controls spanning the device, software, data, and network levels were implemented and verified through testing. MSK Go was found to conform to applicable cybersecurity requirements.

MSK Go incorporates artificial intelligence and machine learning (AI/ML) functionality. The AI/ML model is based on AlphaCNN, a proprietary multi-task convolutional neural network implementing non-adaptive machine learning algorithms for real-time anatomical structure detection and segmentation of B-mode ultrasound images. AI/ML performance verification was conducted using a sequestered test dataset of 17,746 images from 40 subjects, independent from development data at the subject level. Performance was evaluated against a three-reader expert-defined reference standard across four endpoints: anatomical structure detection, anatomical structure highlighting via Dice similarity coefficient, joint view detection, and detection indicator accuracy.

Summary of Clinical Performance Testing

A prospectively acquired ultrasound image dataset spanning five joint regions (Shoulder, Elbow, Wrist & Hand, Knee, Ankle & Foot) was used for clinical validation. All images had expert-annotated reference standards for joint view classification, anatomical structure detection, and segmentation. Images were captured by licensed healthcare professionals at three U.S. clinical sites. The validation dataset was independent from the development dataset in all aspects. A total of 15,600 images from 3,017 ultrasound scans of 79 subjects were included in the analysis.

The validation dataset included representation across key demographic and clinical variables as summarized below:

Category	Subgroup	%
Ethnicity	Hispanic or Latino	38
	Not Hispanic or Latino	62
Race	American Indian or Alaska Native	5
	Asian	10
	Black or African American	20
	Native Hawaiian or Pacific Islander	2
	White	63
Gender	Female	54
	Male	46
BMI	< 30 (17.27–29.9)	64
	$\geq$ 30 (30–50.9)	36
Age (years)	18–34	47
	35–49	23
	50–64	21
	$\geq$ 65	9
Sonographic Finding	Present in at least one joint	62
	Not present	38

MSK Go software outputs were compared post hoc against a clinical reference standard established by four musculoskeletal ultrasound experts using consensus-based adjudication. The evaluated features included: (1) joint view detection, (2) anatomical structure detection, (3) anatomical structure segmentation (highlighting), and (4) detection indicator. Detection performance was assessed using Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA); segmentation performance was assessed using the Dice Similarity Coefficient. All two-sided 95% confidence intervals were calculated using a clustered bootstrap resampling methodology, with subjects treated as the primary sampling unit.

Joint view detection was evaluated across 39 supported views. Mean PPA across all views of each joint ranged from 0.95 to 1.00 and mean NPA from 0.98 to 1.00, with elbow achieving perfect agreement across all evaluated views.

Anatomical structure detection was evaluated across 120 structures in 39 views, where a Dice threshold of 0.5 was used to define agreement. Mean PPA across all structures within each joint ranged from 0.93 to 0.95 and mean NPA from 0.98 to 0.99, with NPA remaining above 0.85 for all evaluated structures. The detection indicator, which reflects the completeness of supported structures detected, demonstrated performance consistent with structure detection, with PPA ranging from 0.90 to 1.00 and NPA from 0.97 to 1.00 across all joints and indicator levels.

Segmentation performance was assessed using the Dice Similarity Coefficient. Mean Dice scores across all structures within each joint ranged from 0.80 to 0.84, with no individual structure demonstrating a mean Dice value below 0.70 across any joint or view.

Subgroup analyses across race, age, sex, BMI, ethnicity, clinical site, and sonographic patient status demonstrated consistent performance across all evaluated endpoints. The presence of sonographic findings did not adversely affect device performance, and no clinically meaningful differences were observed across subgroups.

The non-clinical and clinical performance testing results for MSK Go across all five supported joint regions are relevant to a determination of substantial equivalence. The results demonstrate that MSK Go performs within the range established by the predicate device (Clarius AI, K222406) for non-invasive processing of ultrasound images using automatic image segmentation and highlighting of anatomical structures utilizing artificial intelligence algorithms, and that any differences in anatomical site or indications for use do not raise new questions of safety or effectiveness.

Predetermined Change Control Plan (PCCP)

Modifications to MSK Go will be made in accordance with its Predetermined Change Control Plan (PCCP). The PCCP provides a description of the planned modification, a modification protocol defining the methods used to verify, validate, and implement the modification in a controlled manner, and an impact assessment evaluating the potential effects of the modification on device safety and effectiveness.

MSK Go operates on ultrasound image data acquired from compatible ultrasound systems. The PCCP provides a description of the device's planned modifications for extending the compatibility to additional ultrasound systems that meet predefined regulatory, technical, and imaging specifications. This modification is limited to system integration and image input/output handling and does not involve any changes to the AI/ML algorithms, model architecture, training parameters, training data, or intended use of the device.

Modification	Rationale	Testing / Validation Methods	Impact Assessment
Extending the use of AI-DSF with additional ultrasound systems	To enable deployment of MSK Go on additional FDA-cleared ultrasound systems that meet predefined specifications, thereby increasing availability without modifying the AI/ML model	System-specific verification and validation using fully sequestered test datasets; performance evaluation using the same metrics, statistical analysis framework, and acceptance criteria as the original device; no retraining or model modification	Benefits: Broader device compatibility and availability while maintaining consistent performance. Risks: Variability of image characteristics from new ultrasound systems used as input source could impact AI/ML performance. Risk Mitigation: System-specific verification and validation against predefined acceptance criteria; integrations not meeting criteria are not released under the PCCP.

Under the PCCP, each additional ultrasound system integration is evaluated independently using system-specific verification and validation activities. Performance evaluation is conducted using fully sequestered test datasets collected on the new ultrasound system, following the same data management practices, reference standard determination, performance metrics, statistical analysis plan, and acceptance criteria established for the originally cleared device. No AI/ML model retraining or tuning is performed as part of this PCCP. If predefined acceptance criteria are not met, the integration is not released under the PCCP. Implementation of the modification does not involve software updates to previously deployed systems. Instead, MSK Go is

deployed through controlled installation at the time of integration with a new ultrasound system. Post-market monitoring, complaint handling, and vigilance activities remain unchanged from those applied to the originally cleared device.

Conclusion

The subject device and the predicate device have the same intended use and similar technological characteristics. Any differences in indications for use or technological characteristics between the subject device and the legally marketed predicate device do not raise new questions of safety or effectiveness. Based on the information provided in this submission, the subject device is substantially equivalent to the predicate device and is therefore as safe and effective as the legally marketed device.