

**K260234 MSK Go**May 21, 2026  
115 days to decisionK260234 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k260234/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jan 26, 2026
Decision date	May 21, 2026
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Smart Alfa Teknoloji San. Ve Tic. A.S.</b>
Location	Ankara, TR
Contact	Utku Kaya
510(k) history	2 submissions · 2 cleared · 2025-2026

**CLINICAL EVIDENCE - NCT07336407****Data Collection for the Validation of an Artificial Intelligence Software to Support Musculoskeletal Ultrasound Examination**

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Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	79 patients (actual)
Study sites	3 sites
Condition studied	Ultrasound Imaging of Anatomical Structures
Primary purpose	Diagnostic
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Nov 30, 2025
Sponsor	Smart Alfa Teknoloji San. ve Tic. A.S. (Industry)

**Primary outcome**

Rate of spatial (area) overlap of anatomical structure areas on the ultrasound image

**Secondary outcome**

Rate of correctly assigning anatomical structure completeness level for any scan view of the joint

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT07336407](https://clinicaltrials.gov/study/NCT07336407)