

K233196 Medihub ProstateJun 21, 2024
267 days to decisionK233196 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k233196/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Sep 28, 2023
Decision date	Jun 21, 2024
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	JLK, Inc.
Location	Seoul, KR
Contact	Dongmin Kim
510(k) history	8 submissions · 8 cleared · 2024-2026

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	John J. Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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