FDA 510(k) Premarket Notification

K260497 DEEPVESSEL Plaque

CLEARED

Jun 4, 2026
111 days to decision

K260497 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k260497/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Feb 13, 2026
Decision date	Jun 4, 2026
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Keya Medical Technology Co., Ltd.**
Location	Beijing, CN
Contact	Ning Li
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells**
Contact	Kelliann Payne

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