

K250237 InferOperate SuiteSep 15, 2025
231 days to decisionK250237 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k250237/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jan 27, 2025
Decision date	Sep 15, 2025
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	Beijing Infervision Healthcare Medical Technology Co., Ltd.
Location	Beijing, CN
Contact	Matt Deng
510(k) history	2 submissions · 2 cleared · 2025-2026

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