

K230497 Bladder AI (AIBV01)Jun 22, 2023
118 days to decisionK230497 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k230497/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Feb 24, 2023
Decision date	Jun 22, 2023
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Exo, Inc.
Location	Walker, MI, US
Contact	Jacqueline Murray
510(k) history	5 submissions · 5 cleared · 1983-2025

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