

K230986 Bladder ScannerDec 29, 2023
267 days to decisionK230986 · Product code: IYO · Radiology
Source: <https://www.510kdatabase.net/k230986/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Apr 6, 2023
Decision date	Dec 29, 2023
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Avantsonic Technology Co., Ltd.
Location	Chongqing, CN
Contact	Winnie Wang
510(k) history	2 submissions · 2 cleared · 2018-2023

REGULATORY CONSULTANT

Consulting firm	Beijing Believe-Med Technology Service Co., Ltd.
Contact	Ray Wang

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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