

**K223448 Bladder Scanner Model: BVT02**Jul 7, 2023  
234 days to decisionK223448 · Product code: IYO · Radiology  
Source: <https://www.510kdatabase.net/k223448/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Nov 15, 2022
Decision date	Jul 7, 2023
Days to decision	234 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Xuzhou Kaixin Electronic Instrument Co., Ltd.</b>
Location	Xuzhou, CN
Contact	Chunmei Xu
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shenzhen Hlongmed Biotech Co., Ltd.</b>
Contact	Long Yang

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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