

**K231354 Pocket Ultrasound System (C10)**Dec 20, 2023  
224 days to decisionK231354 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k231354/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	May 10, 2023
Decision date	Dec 20, 2023
Days to decision	224 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Beijing Konted Medical Technology Co.,Ltd</b>
Location	Beijing, CN
Contact	Deyi Zhu
510(k) history	2 submissions · 2 cleared · 2023-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Sungo Management Consulting Company Limited.</b>
Contact	Ivy 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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