

**K210591 Palm Bladder Scanner - PBSV7.1**Jun 9, 2021  
100 days to decisionK210591 · Product code: IYO · Radiology  
Source: <https://www.510kdatabase.net/k210591/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Mar 1, 2021
Decision date	Jun 9, 2021
Days to decision	100 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mianyang Meike Electronic Equipment Co., Ltd.</b>
Location	Wenzhou, Zhejiang, CN
Contact	Wenjun Zhao
510(k) history	3 submissions · 3 cleared · 2013-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Wenzhou Cytech Information Service Co., Ltd.</b>
Contact	Helen Nan

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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