

**K213488 Bladder Scanner, Model Name:M5**Jul 1, 2022  
242 days to decisionK213488 · Product code: IYO · Radiology  
Source: <https://www.510kdatabase.net/k213488/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Nov 1, 2021
Decision date	Jul 1, 2022
Days to decision	242 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Suzhou Peaksonic Medical Technology Co., Ltd.</b>
Location	Qiandeng, Kunshan, Suzhou, CN
Contact	Calvin Ma
510(k) history	2 submissions · 2 cleared · 2021-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213488/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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