

K201316 Bladder Scanner (Model: M3, M3-HD, M4, M4-HD)Feb 26, 2021
284 days to decisionK201316 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k201316/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	May 18, 2020
Decision date	Feb 26, 2021
Days to decision	284 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201316/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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