

K180636 ExactVu High Resolution Micro-Ultrasound SystemApr 30, 2018
49 days to decisionK180636 · Product code: IYO · Radiology
Source: <https://www.510kdatabase.net/k180636/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Mar 12, 2018
Decision date	Apr 30, 2018
Days to decision	49 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Exact Imaging, Inc.
Location	Markham, CA
Contact	Randy AuCoin
510(k) history	3 submissions · 3 cleared · 2018-2019

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	MARK JOB

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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