

**K192303 ExactVu High Resolution Micro-Ultrasound System**Oct 1, 2019  
39 days to decisionK192303 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k192303/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Aug 23, 2019
Decision date	Oct 1, 2019
Days to decision	39 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Exact Imaging, Inc.</b>
Location	Markham, CA
Contact	Sam Rajkumar
510(k) history	3 submissions · 3 cleared · 2018-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
Contact	Prithul Bom

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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