

K190995 ExactVu High Resolution Micro-Ultrasound SystemMay 10, 2019
24 days to decisionK190995 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k190995/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Apr 16, 2019
Decision date	May 10, 2019
Days to decision	24 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

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