

K190447 7400 Ultrasound Systems

Apr 1, 2019
35 days to decision

K190447 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k190447/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Feb 25, 2019
Decision date	Apr 1, 2019
Days to decision	35 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Navigant Consulting - on Behalf of Esaote S.P.A.
Location	Indianapolis, IN, US
Contact	Allison Scott
510(k) history	1 submissions · 1 cleared · 2019-2019

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k190447/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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