

**K232336 ES Series V2**Sep 26, 2023  
53 days to decisionK232336 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k232336/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Aug 4, 2023
Decision date	Sep 26, 2023
Days to decision	53 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>E-Scopics</b>
Location	Aix-En-Provence, FR
Contact	Claude Cohen Bacrie
Website	<a href="https://www.e-scopics.com">https://www.e-scopics.com</a>
510(k) history	3 submissions · 3 cleared · 2022-2026

E-Scopics is a medical device company specializing in software-based Radiology imaging systems. The company operates with a manufacturing facility in Aix-En-Provence, France. E-Scopics develops dematerialized ultrasound platforms that transform standard consumer devices into diagnostic imaging tools through proprietary software and ultra-low power digital transducers. The company has received FDA 510(k) clearances from total submissions, with all submissions focused on Radiology devices. E-Scopics achieved its first FDA 510(k) clearance in 2022 and most recently in 2026, ...