

**K260748 ES-Series**Jun 9, 2026  
95 days to decisionK260748 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k260748/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Mar 6, 2026
Decision date	Jun 9, 2026
Days to decision	95 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>E-Scopics</b>
Location	Aix-En-Provence, FR
Contact	Aurelie Gruener
Website	<a href="https://www.e-scopics.com">https://www.e-scopics.com</a>
510(k) history	4 submissions · 4 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, ...

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