

K260589 ES-SeriesApr 29, 2026
68 days to decisionK260589 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k260589/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Feb 20, 2026
Decision date	Apr 29, 2026
Days to decision	68 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	E-Scopics
Location	Aix-En-Provence, FR
Contact	Aurelie Gruener
Website	https://www.e-scopics.com
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, ...