

K213102 ES1 SystemJan 11, 2022
109 days to decisionK213102 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k213102/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Sep 24, 2021
Decision date	Jan 11, 2022
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	E-Scopics
Location	Aix-En-Provence, FR
Contact	Claude Cohen-Bacrie
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, ...