

**K060956 G-SCAN-MODEL 9800020000, E-SCAN MODEL  
9800010000 AND E-SCAN XQ-  
MODELS-9800010011/9800010005,9800010009/9800010004**May 4, 2006  
27 days to decisionK060956 · Product code: LNH · Radiology  
Source: <https://www.510kdatabase.net/k060956/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Apr 7, 2006
Decision date	May 4, 2006
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Esaote, S.P.A.</b>
Location	Genoa, IT
Contact	CARRI GRAHAM
Website	<a href="https://www.esaote.com">https://www.esaote.com</a>
510(k) history	67 submissions · 67 cleared · 2003-2026

Esaote, S.P.A. is a medical diagnostic imaging company based in Genoa, Italy. The company specializes in ultrasound, MRI, and healthcare IT solutions for clinical settings. Esaote has received FDA 510(k) clearances from total submissions since 2003. The company's regulatory portfolio is dominated by Radiology devices, representing 100% of its FDA submissions. Recent cleared devices include the MyLab ultrasound systems and Magnifico Open imaging platforms. The company remains actively engaged in FDA regulatory submissions, with the latest clearance in 2026. Esaote's produc...