

**K122006 G-SCAN BRIO**Aug 6, 2012  
28 days to decisionK122006 · Product code: **LNH** · Radiology  
Source: <https://www.510kdatabase.net/k122006/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Jul 9, 2012
Decision date	Aug 6, 2012
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Esaote, S.P.A.</b>
Location	Genoa, IT
Contact	ALLISON SCOTT, RAC
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...

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