

**K083358 LUBRICANO-ULTRASOUND**Jan 9, 2009  
87 days to decisionK083358 · Product code: **MUI** · Radiology  
Source: <https://www.510kdatabase.net/k083358/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Coupling, Ultrasound (MUI)
Date received	Oct 14, 2008
Decision date	Jan 9, 2009
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Farco Pharma GmbH</b>
Location	Washington, DC, US
Contact	SETH A MAILHOT
510(k) history	2 submissions · 2 cleared · 2008-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083358/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 17, 2026