

**K163119 NaviSuite SSI Edition**May 1, 2017  
174 days to decisionK163119 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k163119/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Nov 8, 2016
Decision date	May 1, 2017
Days to decision	174 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medcom GmbH</b>
Location	Darmstadt, Hessen, DE
Contact	JOHANNES MESSOW
510(k) history	11 submissions · 11 cleared · 2002-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163119/> 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 16, 2026