

**K173574 DenSeeMammo**Jun 26, 2018  
218 days to decisionK173574 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k173574/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Nov 20, 2017
Decision date	Jun 26, 2018
Days to decision	218 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Statlife</b>
Location	Villejuif, FR
Contact	Stephane Ragusa
510(k) history	2 submissions · 2 cleared · 2016-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173574/> 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