

**K152009 DENSEEMAMMO v1.0**Dec 5, 2016  
503 days to decisionK152009 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k152009/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 21, 2015
Decision date	Dec 5, 2016
Days to decision	503 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152009/> 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