

**K161479 hipEOS**Jun 28, 2016  
28 days to decisionK161479 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k161479/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Image Processing, Radiological (LLZ)
Date received	May 31, 2016
Decision date	Jun 28, 2016
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Onefit Medical</b>
Location	Besançon, FR
Contact	Julien SIMON
510(k) history	5 submissions · 5 cleared · 2014-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161479/> 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