

**K163687 OLINDA EXM**Jul 19, 2017  
203 days to decisionK163687 · Product code: **IYX** · Radiology  
Source: <https://www.510kdatabase.net/k163687/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Scintillation (gamma) (IYX)
Date received	Dec 28, 2016
Decision date	Jul 19, 2017
Days to decision	203 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hermes Medical Solutions AB</b>
Location	Stockholm, SE
Contact	Joakim Arwidson
510(k) history	16 submissions · 16 cleared · 2012-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163687/> 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 26, 2026