

**K140380 OPERA SWING**Sep 26, 2014  
224 days to decisionK140380 · Product code: **JAA** · Radiology  
Source: <https://www.510kdatabase.net/k140380/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Feb 14, 2014
Decision date	Sep 26, 2014
Days to decision	224 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>General Medical Merate S.P.A</b>
Location	Seriate, Bergamo, IT
Contact	BERTHOIN CLAUDE
510(k) history	7 submissions · 7 cleared · 1982-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k140380/> 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