

**K140013 SOPIX INSIDE, SOPIX2 INSIDE**Sep 5, 2014  
246 days to decisionK140013 · Product code: **MUH** · Radiology  
Source: <https://www.510kdatabase.net/k140013/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Jan 2, 2014
Decision date	Sep 5, 2014
Days to decision	246 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Sopro - Acteon Group</b>
Location	Mt. Laurel, NJ, US
Contact	RICK ROSATI
510(k) history	4 submissions · 4 cleared · 2014-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k140013/> 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