

**K151053 PSPIX 2 scanner, Imaging Plate Size 0 for PSPIX2 scanner, Imaging Plate Size 1 for PSPIX2 scanner, Imaging Plate Size 2 for PSPIX2 scanner, Imaging Plate Size 3 for PSPIX2 scanner**Jul 31, 2015  
102 days to decisionK151053 · Product code: **MUH** · Radiology  
Source: <https://www.510kdatabase.net/k151053/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Apr 20, 2015
Decision date	Jul 31, 2015
Days to decision	102 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	PHILIPPE BOYER
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/k151053/> 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