

**K122806 IMAGE WORKS PANOURA**Mar 8, 2013  
176 days to decisionK122806 · Product code: **MUH** · Radiology  
Source: <https://www.510kdatabase.net/k122806/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Sep 13, 2012
Decision date	Mar 8, 2013
Days to decision	176 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mic International</b>
Location	Tokyo, JP
Contact	IZUMI MARUO
510(k) history	1 submissions · 1 cleared · 2013-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122806/> 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 17, 2026