

**K103483 INGENUITY TF PET/MR**Nov 23, 2011  
362 days to decisionK103483 · Product code: **OUO** · Radiology  
Source: <https://www.510kdatabase.net/k103483/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomographic Imager Combining Emission Computed Tomography With Nuclear Magnetic Resonance (OUO)
Date received	Nov 26, 2010
Decision date	Nov 23, 2011
Days to decision	362 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Philips Healthcare (Cleveland)</b>
Location	Cleveland, OH, US
Contact	EDUARD TOEREK
510(k) history	6 submissions · 6 cleared · 2011-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103483/> 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