

**K152867 MHI-TM2000 Linear Accelerator System, VERO, Imavis**Oct 21, 2015  
21 days to decisionK152867 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k152867/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Sep 30, 2015
Decision date	Oct 21, 2015
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mitsubishi Heavy Industries, Ltd.</b>
Location	Hiroshima-Shi, JP
Contact	KATSUHISA TOYAMA
Website	<a href="http://www.mhi-global.com/">http://www.mhi-global.com/</a>
510(k) history	3 submissions · 3 cleared · 2007-2015

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152867/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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