

**K100264 T-FORM EXTREMITY IMMOBILIZER, MODEL RT-6060**Apr 9, 2010  
71 days to decisionK100264 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k100264/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Jan 28, 2010
Decision date	Apr 9, 2010
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bionix Development Corp.</b>
Location	Toledo, OH, US
Contact	JAMES HUTTNER
510(k) history	12 submissions · 12 cleared · 1990-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100264/> 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