

**K100691 OMNI V SBRT POSITIONING SYSTEM, MODEL RT-4500**May 11, 2010  
62 days to decisionK100691 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k100691/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Mar 10, 2010
Decision date	May 11, 2010
Days to decision	62 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/k100691/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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