

**K111613 XELIS FUSION**Sep 8, 2011  
91 days to decisionK111613 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k111613/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jun 9, 2011
Decision date	Sep 8, 2011
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Infinitt Co., Ltd.</b>
Location	Denton, TX, US
Contact	CARL ALLETTO
510(k) history	12 submissions · 12 cleared · 2004-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111613/> 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