

**K160108 Synapse PACS**Feb 3, 2016  
15 days to decisionK160108 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k160108/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jan 19, 2016
Decision date	Feb 3, 2016
Days to decision	15 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fujifilm Medical Systems U.S.A, Inc.</b>
Location	Stamford, CT, US
Contact	Jyh-Shyan Lin
510(k) history	39 submissions · 39 cleared · 2005-2018

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