

**K171463 ASPIRE Bellus II**Sep 29, 2017  
134 days to decisionK171463 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k171463/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	May 18, 2017
Decision date	Sep 29, 2017
Days to decision	134 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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