

K153166 Fusion BxJan 25, 2016
84 days to decisionK153166 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k153166/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Nov 2, 2015
Decision date	Jan 25, 2016
Days to decision	84 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Focal Healthcare, Inc.
Location	Toronto, CA
Contact	MAHAM ANSARI
510(k) history	1 submissions · 1 cleared · 2016-2016

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