

**K152321 kVue Encompass SRS Insert (Encompass Insert),  
Encompass SRS Standalone (Encompass Device), Encompass  
SRS MRI Immobilization device (Encompass MRI Device,  
Encompass Intracranial Fibreplast Variable Perf Head Only  
Open View System, Encompass Intracranial Fibreplast Variable  
Perf Head Only Open View with 119 mm opening**Dec 4, 2015  
109 days to decisionK152321 · Product code: IYE · Radiology  
Source: <https://www.510kdatabase.net/k152321/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Aug 17, 2015
Decision date	Dec 4, 2015
Days to decision	109 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Qfix</b>
Location	Avondale, PA, US
Contact	NADIA SOOKDEO HARHEN
510(k) history	7 submissions · 7 cleared · 2015-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152321/> 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 27, 2026