

**K173744 ProFuse CAD**Nov 21, 2018  
349 days to decisionK173744 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k173744/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Dec 7, 2017
Decision date	Nov 21, 2018
Days to decision	349 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Eigen</b>
Location	Nevada City, CA, US
Contact	William Mandel
510(k) history	16 submissions · 16 cleared · 1988-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173744/> 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 26, 2026