

**K193417 FractureDetect (FX)**Jul 30, 2020  
234 days to decisionK193417 · Product code: **QBS** · Radiology  
Source: <https://www.510kdatabase.net/k193417/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer Assisted Detection/diagnosis Software For Fracture (QBS)
Date received	Dec 9, 2019
Decision date	Jul 30, 2020
Days to decision	234 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Imagen Technologies, Inc.</b>
Location	New York, NY, US
Contact	Robert Lindsey
510(k) history	6 submissions · 5 cleared · 2018-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193417/> 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