

K181290 Fusion Bx 2.0Jun 15, 2018
30 days to decisionK181290 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k181290/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Image Processing, Radiological (LLZ)
Date received	May 16, 2018
Decision date	Jun 15, 2018
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Focal Healthcare, Inc.
Location	Toronto, CA
Contact	Karen Zhou
510(k) history	1 submissions · 1 cleared · 2018-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181290/> Data sourced from FDA 510(k) public records (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. - Generated May 16, 2026