

K191495 Biopsy PositionerJul 3, 2019
28 days to decisionK191495 · Product code: **IZH** · Radiology
Source: <https://www.510kdatabase.net/k191495/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Mammographic (IZH)
Date received	Jun 5, 2019
Decision date	Jul 3, 2019
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fujifilm Corporation
Location	Ashigara Kami-Gun, JP
Contact	Randy Vader
510(k) history	62 submissions · 62 cleared · 2018-2026

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