

**K110202 FUJIFILM DIAGNOSTIC ULTRASOUND SYSTEM
FAZONE CB**Feb 8, 2011
15 days to decisionK110202 · Product code: **ITX** · Radiology
Source: <https://www.510kdatabase.net/k110202/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Transducer, Ultrasonic, Diagnostic (ITX) |
| Date received | Jan 24, 2011 |
| Decision date | Feb 8, 2011 |
| Days to decision | 15 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Fujifilm Medical System U.S.A., Inc. |
| Location | Stamford, CT, US |
| Contact | KATHERINE Y CHOI |
| 510(k) history | 71 submissions · 71 cleared · 1988-2017 |

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