

**K231666 Endoscopic Ultrasonic Probe (P2612S-L)**Dec 13, 2023  
189 days to decisionK231666 · Product code: **ITX** · Radiology  
Source: <https://www.510kdatabase.net/k231666/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Jun 7, 2023
Decision date	Dec 13, 2023
Days to decision	189 days
Third-party review	No
Summary / Statement	Summary
Other names	Endoscopic Ultrasonic Probe (P2620S-L)

**APPLICANT**

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Company	<b>Fujifilm Healthcare Americas Corporation</b>
Location	Lexington, MA, US
Contact	Chaitrali Kulkarni
510(k) history	12 submissions · 12 cleared · 2023-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231666/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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