

K153206 Fujifilm Ultrasonic Processors SU-1 PLATINUM and SU-1Mar 3, 2016
119 days to decisionK153206 · Product code: **FDS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k153206/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastroscope And Accessories, Flexible/rigid (FDS)
Date received	Nov 5, 2015
Decision date	Mar 3, 2016
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153206/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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