FDA 510(k) Premarket Notification

CLEARED

K171207 FUJIFILM Ultrasonic Processor SP-900 and FUJIFILM Ultrasonic Probe PB2020-M

Jan 11, 2018
261 days to decision

K171207 · Product code: **ODG** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k171207/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Ultrasound System, Gastroenterology-urology (ODG)
Date received	Apr 25, 2017
Decision date	Jan 11, 2018
Days to decision	261 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Fujifilm Medical Systems U.S.A, Inc.**
Location	Stamford, CT, US
Contact	Jeffrey Wan
510(k) history	39 submissions · 39 cleared · 2005-2018