FDA 510(k) Premarket Notification

K133976 FUJIFILM ENDOSCOPIC CO2 REGULATOR

CLEARED

Sep 9, 2014
257 days to decision

K133976 · Product code: **FCX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k133976/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Automatic Carbon-dioxide For Endoscope (FCX)
Date received	Dec 26, 2013
Decision date	Sep 9, 2014
Days to decision	257 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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