FDA 510(k) Premarket Notification

K150221 EPX-4440HD and EPX-4400HD with FICE

CLEARED

Oct 1, 2015
244 days to decision

K150221 · Product code: **FET** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k150221/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Video Imaging System/component, Gastroenterology-urology (FET)
Date received	Jan 30, 2015
Decision date	Oct 1, 2015
Days to decision	244 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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