FDA 510(k) Premarket Notification

K142629 EG-530CT, EG-530D, EC-530DL, and ES-530WE Endoscopes

CLEARED

May 14, 2015
240 days to decision

K142629 · Product code: **FDS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k142629/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastroscope And Accessories, Flexible/rigid (FDS)
Date received	Sep 16, 2014
Decision date	May 14, 2015
Days to decision	240 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