FDA 510(k) Premarket Notification

K171673 Focus Cap

CLEARED

Jan 19, 2018
227 days to decision

K171673 · Product code: **FDF** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k171673/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Jun 6, 2017
Decision date	Jan 19, 2018
Days to decision	227 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Gce Medical Corporation**
Location	Fresno, CA, US
Contact	Stanley Chang
510(k) history	1 submissions · 1 cleared · 2018-2018