FDA 510(k) Premarket Notification

K162332 Nexcore GI Insufflator

CLEARED

Sep 29, 2016
41 days to decision

K162332 · Product code: **FCX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k162332/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Automatic Carbon-dioxide For Endoscope (FCX)
Date received	Aug 19, 2016
Decision date	Sep 29, 2016
Days to decision	41 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Nexcore Technology, LLC**
Location	Winchester, MA, US
Contact	Julie Broderick
510(k) history	1 submissions · 1 cleared · 2016-2016