FDA 510(k) Premarket Notification

K181020 Cytosponge Cell Collection Device

CLEARED

Aug 16, 2018
121 days to decision

K181020 · Product code: **EOX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k181020/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Esophagoscope (flexible Or Rigid) (EOX)
Date received	Apr 17, 2018
Decision date	Aug 16, 2018
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Covidien, LLC**
Location	Mansfield, MA, US
Contact	Rachel Silva
510(k) history	88 submissions · 85 cleared · 2010-2026