FDA 510(k) Premarket Notification

K182159 Strome-Blitzer Cytology Balloon

CLEARED

Jun 13, 2019
308 days to decision

K182159 · Product code: **EOX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k182159/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Esophagoscope (flexible Or Rigid) (EOX)
Date received	Aug 9, 2018
Decision date	Jun 13, 2019
Days to decision	308 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Adn International, LLC**
Location	New York, NY, US
Contact	Marshall Strome
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**AlvaMed, Inc.**
Contact	Eric Bannon

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov