FDA 510(k) Premarket Notification

K182253 FUJIFILM Video Bronchoscopes

CLEARED

Apr 4, 2019
227 days to decision

K182253 · Product code: **EOQ** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k182253/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope (flexible Or Rigid) (EOQ)
Date received	Aug 20, 2018
Decision date	Apr 4, 2019
Days to decision	227 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fujifilm Corporation**
Location	Ashigara Kami-Gun, JP
Contact	Randy Vader
510(k) history	63 submissions · 63 cleared · 2018-2026

REGULATORY CONSULTANT

Consulting firm	**Fujifilm Medical Systems U.S.A, Inc.**
Contact	Jeffrey Wan

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