FDA 510(k) Premarket Notification

K220957 FUJIFILM Endoscope Model EB-710P

CLEARED

Nov 10, 2022
223 days to decision

K220957 · Product code: **EOQ** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k220957/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope (flexible Or Rigid) (EOQ)
Date received	Apr 1, 2022
Decision date	Nov 10, 2022
Days to decision	223 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fujifilm Corporaton**
Location	Tokyo, JP
Contact	Randy Vader
510(k) history	6 submissions · 6 cleared · 2020-2023

REGULATORY CONSULTANT

Consulting firm	**FUJIFILM Healthcare Americas Corporation**
Contact	Kotei Aoki

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