FDA 510(k) Premarket Notification

K210379 Broncho Videoscope System

CLEARED

Jul 28, 2021
169 days to decision

K210379 · Product code: **EOQ** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k210379/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope (flexible Or Rigid) (EOQ)
Date received	Feb 9, 2021
Decision date	Jul 28, 2021
Days to decision	169 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Scivita Medical Technology Co., Ltd.**
Location	Suzhou, CN
Contact	Ruqin Wu
510(k) history	12 submissions · 12 cleared · 2019-2026

REGULATORY CONSULTANT

Consulting firm	**Mid-Link Consulting Co, Ltd.**
Contact	Diana Hong

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