FDA 510(k) Premarket Notification

K221302 Recon Steerable Sheath

CLEARED

Aug 15, 2022
102 days to decision

K221302 · Product code: **EOQ** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k221302/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope (flexible Or Rigid) (EOQ)
Date received	May 5, 2022
Decision date	Aug 15, 2022
Days to decision	102 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Serpex Medical, Inc.**
Location	Santa Clara, CA, US
Contact	Sasha Schrode
510(k) history	3 submissions · 3 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	**Honkanen Consulting, Inc.**
Contact	Laurie Lewandowski

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