CLEARED

K213235 PENTAX Medical ONE Pulmo Single Use Video Bronchoscope System

Dec 21, 2022
447 days to decision

K213235 · Product code: **EOQ** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k213235/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope (flexible Or Rigid) (EOQ)
Date received	Sep 30, 2021
Decision date	Dec 21, 2022
Days to decision	447 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Pentax of America, Inc.**
Location	West Cadwell, NJ, US
Contact	William Goeller
510(k) history	44 submissions · 44 cleared · 2012-2025