

**K213235 PENTAX Medical ONE Pulmo Single Use Video Bronchoscope System**Dec 21, 2022  
447 days to decisionK213235 · Product code: **EOQ** · Ear, Nose, ThroatSource: <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	<b>Pentax of America, Inc.</b>
Location	West Cadwell, NJ, US
Contact	William Goeller
510(k) history	44 submissions · 44 cleared · 2012-2025

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213235/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026