

**K183516 PENTAX Medical Ultrasound Video Bronchoscope
EB19-J10U**Sep 6, 2019
262 days to decisionK183516 · Product code: **EOQ** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k183516/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope (flexible Or Rigid) (EOQ)
Date received	Dec 18, 2018
Decision date	Sep 6, 2019
Days to decision	262 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

REGULATORY CONSULTANT

Consulting firm	Namsa, Inc.
Contact	Beryl St. Jeanne

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183516/> Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026