

K232860 PENTAX Medical Video Processor EPK-i8020c, PENTAX Medical Video Bronchoscope EB11-J10, PENTAX Medical Video Bronchoscope EB15-J10, PENTAX Medical Video Bronchoscope EB19-J10U, PENTAX Medical Ultrasound Video Bronchoscope EB19-J10U

Jan 18, 2024
125 days to decision

K232860 · Product code: **EOQ** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k232860/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope (flexible Or Rigid) (EOQ)
Date received	Sep 15, 2023
Decision date	Jan 18, 2024
Days to decision	125 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k232860/>, Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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