

K210928 PENTAX Medical Video Bronchoscope EB11-J10

Oct 21, 2021
206 days to decision

K210928 · Product code: **EOQ** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k210928/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope (flexible Or Rigid) (EOQ)
Date received	Mar 29, 2021
Decision date	Oct 21, 2021
Days to decision	206 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/k210928/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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