

**K183654 PENTAX Medical EB-1970UK Ultrasound Video  
Bronchoscope + Hitachi NOBLUS and HI VISION Preirus**May 23, 2019  
147 days to decisionK183654 · Product code: **EOQ** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k183654/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Bronchoscope (flexible Or Rigid) (EOQ)
Date received	Dec 27, 2018
Decision date	May 23, 2019
Days to decision	147 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183654/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026