FDA 510(k) Premarket Notification

K183516 PENTAX Medical Ultrasound Video Bronchoscope EB19-J10U

CLEARED

Sep 6, 2019
262 days to decision

K183516 · 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