

K183691 PENTAX Medical ENT Video Imaging SystemJun 12, 2019
163 days to decisionK183691 · Product code: **EOB** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k183691/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Nasopharyngoscope (flexible Or Rigid) (EOB)
Date received	Dec 31, 2018
Decision date	Jun 12, 2019
Days to decision	163 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

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