

**K203166 PENTAX Medical Ultrasound Upper GI Video Scope
EG34-J10U, PENTAX Medical Ultrasound Upper GI Video Scope
EG36-J10UR, PENTAX Medical Ultrasound Upper GI Video
Scope EG38-J10UT, PENTAX Medical Ultrasound Video
Bronchoscope EB19-J10U**

Dec 30, 2020
68 days to decision

K203166 · Product code: **ODG** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k203166/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscopic Ultrasound System, Gastroenterology-urology (ODG)
Date received	Oct 23, 2020
Decision date	Dec 30, 2020
Days to decision	68 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	Mic International
Contact	Fumiaki Kanai

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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Device record: <https://www.510kdatabase.net/k203166/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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