

**K200090 PENTAX Medical EG-J10U Endoscopic Ultrasound System - EG34-J10U Ultrasound Upper GI Video Scope (Convex Array Type), EG36-J10UR Ultrasound Upper GI Video Scope (Radial Array Type), EG38-J10UT Ultrasound Upper GI Video Scope (Convex Array Type)**Jul 23, 2020  
189 days to decisionK200090 · Product code: **ODG** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k200090/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Ultrasound System, Gastroenterology-urology (ODG)
Date received	Jan 16, 2020
Decision date	Jul 23, 2020
Days to decision	189 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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