

**K191282 PENTAX Medical EPK-i7010 and PENTAX EPK-i5010
Video Processors with GI Family**

Nov 8, 2019
179 days to decision

K191282 · Product code: **PEA** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k191282/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope, Accessories, Image Post-processing For Color Enhancement (PEA)
Date received	May 13, 2019
Decision date	Nov 8, 2019
Days to decision	179 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k191282/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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