

**K190805 PENTAX Medical Video Processor EPK-i5500c,  
PENTAX Medical Video Upper GI Scope EG29-i10c, PENTAX  
Medical Video Colonoscope EC34-i10cL, PENTAX Medical  
Video Colonoscope EC38-i10cL**Dec 20, 2019  
266 days to decisionK190805 · Product code: **PEA** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k190805/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope, Accessories, Image Post-processing For Color Enhancement (PEA)
Date received	Mar 29, 2019
Decision date	Dec 20, 2019
Days to decision	266 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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Namsa, Inc.</b>
Contact	Beryl St. Jeanne

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190805/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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