

K150618 PENTAX Medical EPK-i7010 Video Processor with GI Family

Nov 24, 2015
259 days to decision

K150618 · Product code: **PEA** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k150618/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope, Accessories, Image Post-processing For Color Enhancement (PEA)
Date received	Mar 10, 2015
Decision date	Nov 24, 2015
Days to decision	259 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pentax of America, Inc.
Location	West Cadwell, NJ, US
Contact	KRISHNA GOVINDARAJAN
510(k) history	44 submissions · 44 cleared · 2012-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k150618/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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