

K242110 PENTAX Medical Video Colonoscope (EC38-i20cWL)Jan 3, 2025
168 days to decisionK242110 · Product code: **FDF** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k242110/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Jul 19, 2024
Decision date	Jan 3, 2025
Days to decision	168 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	Gurvinder Singh Nanda
510(k) history	44 submissions · 44 cleared · 2012-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242110/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026