K242110 PENTAX Medical Video Colonoscope (EC38-i20cWL)

CLEARED

Jan 3, 2025
168 days to decision

K242110 · Product code: **FDF** · Gastroenterology & Urology
Source: 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