

K241213 PENTAX Medical Video Upper GI Scope (EG27-i20c)Dec 6, 2024
220 days to decisionK241213 · Product code: **FDS** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k241213/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastroscope And Accessories, Flexible/rigid (FDS)
Date received	Apr 30, 2024
Decision date	Dec 6, 2024
Days to decision	220 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	PENTAX Medical Video Colonoscope (EC34-i20cL)

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/k241213/> 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