

**K210485 PENTAX Medical Video Upper GI Scopes (EG Family),
PENTAX Medical Video Colonoscopes (EC Family)**May 13, 2021
83 days to decisionK210485 · Product code: **FDS** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k210485/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastroscope And Accessories, Flexible/rigid (FDS)
Date received	Feb 19, 2021
Decision date	May 13, 2021
Days to decision	83 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	William Goeller
510(k) history	44 submissions · 44 cleared · 2012-2025

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