

K180285 PENTAX Medical Video Colonoscope EC34-i10T SeriesOct 26, 2018
267 days to decisionK180285 · Product code: **FDF** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k180285/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Feb 1, 2018
Decision date	Oct 26, 2018
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pentax Medical of America, Inc.
Location	Montvale, NJ, US
Contact	James W. Monroe
510(k) history	2 submissions · 2 cleared · 2018-2018

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