

K210710 PENTAX Medical Video Duodenoscope ED34-i10T2Apr 9, 2021
30 days to decisionK210710 · Product code: **FDT** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k210710/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Duodenoscope And Accessories, Flexible/rigid (FDT)
Date received	Mar 10, 2021
Decision date	Apr 9, 2021
Days to decision	30 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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