

K202365 Pentax Medical Video Duodenoscope ED32-i10Apr 1, 2021
225 days to decisionK202365 · Product code: **FDT** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k202365/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Duodenoscope And Accessories, Flexible/rigid (FDT)
Date received	Aug 19, 2020
Decision date	Apr 1, 2021
Days to decision	225 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202365/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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