

**K181522 PENTAX MEDICAL ED-3490TK, Video Duodenoscope,
PENTAX Medical ED34-i10T, Video Duodenoscope**Jul 9, 2018
28 days to decision

K181522 · Product code: FDT · Gastroenterology & Urology

Source: <https://www.510kdatabase.net/k181522/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Duodenoscope And Accessories, Flexible/rigid (FDT)
Date received	Jun 11, 2018
Decision date	Jul 9, 2018
Days to decision	28 days
Third-party review	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/k181522/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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