

K163614 PENTAX Medical ED34-i10T, Video DuodenoscopeSep 20, 2017
272 days to decisionK163614 · Product code: **FDT** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k163614/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Duodenoscope And Accessories, Flexible/rigid (FDT)
Date received	Dec 22, 2016
Decision date	Sep 20, 2017
Days to decision	272 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pentax Medical
Location	Montvale, NJ, US
Contact	Kanchana Iyer
510(k) history	6 submissions · 6 cleared · 2013-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k163614/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026