

**K192280 PENTAX Medical ED-3490TK Video Duodenoscope**Oct 21, 2019  
60 days to decisionK192280 · Product code: **FDT** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k192280/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Duodenoscope And Accessories, Flexible/rigid (FDT)
Date received	Aug 22, 2019
Decision date	Oct 21, 2019
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Pentax Medical</b>
Location	Montvale, NJ, US
Contact	William Goeller
510(k) history	6 submissions · 6 cleared · 2013-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192280/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026