

K233942 PENTAX Medical Video Duodenoscope (ED34-i10T2s)Aug 1, 2024
231 days to decisionK233942 · Product code: **FDT** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k233942/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Duodenoscope And Accessories, Flexible/rigid (FDT)
Date received	Dec 14, 2023
Decision date	Aug 1, 2024
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	PENTAX Medical Video Processor (EPK-i8020c); PENTAX Medical Single Use, Sterile Distal End Cap with Elevator (OE-A63); Gas/Water Feeding Valves (OF-B194)

APPLICANT

Company	Pentax of America, Inc.
Location	West Cadwell, NJ, US
Contact	Gurvinder Singh Nanda
510(k) history	44 submissions · 44 cleared · 2012-2025

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