CLEARED

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