FDA 510(k) Premarket Notification

K192280 PENTAX Medical ED-3490TK Video Duodenoscope

CLEARED

Oct 21, 2019
60 days to decision

K192280 · Product code: **FDT** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k192280/

SUBMISSION DETAILS

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

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