FDA 510(k) Premarket Notification

K181084 PENTAX Video Colonoscopes (EC Family)

CLEARED

Jan 18, 2019
269 days to decision

K181084 · Product code: **FDF** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k181084/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Apr 24, 2018
Decision date	Jan 18, 2019
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Pentax of America, Inc.**
Location	West Cadwell, NJ, US
Contact	James W. Monroe
510(k) history	44 submissions · 44 cleared · 2012-2025