FDA 510(k) Premarket Notification

K131902 PENTAX VIDEO UPPER G.I. SCOPES (EG FAMILY)

CLEARED

Apr 10, 2014
289 days to decision

K131902 · Product code: **FDS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k131902/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastroscope And Accessories, Flexible/rigid (FDS)
Date received	Jun 25, 2013
Decision date	Apr 10, 2014
Days to decision	289 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Pentax Medical Company**
Location	Montvale, NJ, US
Contact	KRISHNA GOVINDARAJAN
510(k) history	12 submissions · 12 cleared · 2004-2014