FDA 510(k) Premarket Notification

CLEARED

K083180 THIRD EYE RETROSCOPE AUXILIARY ENDOSCOPY SYSTEM

Feb 12, 2009
107 days to decision

K083180 · Product code: **FDF** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k083180/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Oct 28, 2008
Decision date	Feb 12, 2009
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Avantis Medical Systems, Inc.**
Location	Sunnyvale, CA, US
Contact	AMRITA SETHI
510(k) history	6 submissions · 6 cleared · 2007-2016