FDA 510(k) Premarket Notification

K051068 ZUTRON COLONOSCOPE STIFFENING DEVICE

CLEARED

Jul 11, 2005
76 days to decision

K051068 · Product code: **FDF** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k051068/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Apr 26, 2005
Decision date	Jul 11, 2005
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Zutron Medical**
Location	Lenexa, KS, US
Contact	JORDAN HARTONG
510(k) history	1 submissions · 1 cleared · 2005-2005