FDA 510(k) Premarket Notification

K031758 ACMI M4 TELESCOPES

CLEARED

Sep 2, 2003
88 days to decision

K031758 · Product code: **FBP** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k031758/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Telescope, Rigid, Endoscopic (FBP)
Date received	Jun 6, 2003
Decision date	Sep 2, 2003
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Acmi Corporation**
Location	Southborough, MA, US
Contact	GABRIEL J MURACA
510(k) history	16 submissions · 16 cleared · 2002-2006