FDA 510(k) Premarket Notification

K023358 USA SERIES DUR 8 ELITE, USA SERIES DUR 8, MODELS DUR 8E, DUR 8

CLEARED

Jan 3, 2003
88 days to decision

K023358 · Product code: **FGB** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k023358/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Oct 7, 2002
Decision date	Jan 3, 2003
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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