

**K023358 USA SERIES DUR 8 ELITE, USA SERIES DUR 8,
MODELS DUR 8E, DUR 8**Jan 3, 2003
88 days to decisionK023358 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k023358/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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