

**K093718 ZUTRON MEDICAL ENDOSCOPE LEAK TESTER
MODEL ZUTR-10003**Feb 22, 2010
82 days to decisionK093718 · Product code: **FCY** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k093718/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bulb, Inflation, For Endoscope (FCY)
Date received	Dec 2, 2009
Decision date	Feb 22, 2010
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Zutron Medical, LLC
Location	Lenexa, KS, US
Contact	JORDAN HARTONG
510(k) history	1 submissions · 1 cleared · 2010-2010

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