

**K030854 PROTOCO2L COLON INSUFFLATOR WITH
PERFORMANCE IMPROVEMENTS, MODEL 6400**Apr 16, 2003
29 days to decisionK030854 · Product code: **FCX** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k030854/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Insufflator, Automatic Carbon-dioxide For Endoscope (FCX)
Date received	Mar 18, 2003
Decision date	Apr 16, 2003
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	E-Z-Em, Inc.
Location	Mchenry, IL, US
Contact	JUDY HAUSER
510(k) history	56 submissions · 56 cleared · 1977-2007

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k030854/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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