

K013219 PROTOCO2L INSUFFLATOR MODEL 6400Feb 19, 2002
146 days to decisionK013219 · Product code: **FCX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k013219/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Insufflator, Automatic Carbon-dioxide For Endoscope (FCX)
Date received	Sep 26, 2001
Decision date	Feb 19, 2002
Days to decision	146 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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