

K190985 BAROnova Insufflation System, BAROnova Accessory KitMay 14, 2019
29 days to decisionK190985 · Product code: **FCX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k190985/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Insufflator, Automatic Carbon-dioxide For Endoscope (FCX)
Date received	Apr 15, 2019
Decision date	May 14, 2019
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Baronova, Inc.
Location	San Carlos, CA, US
Contact	Lian Cunningham
510(k) history	3 submissions · 1 cleared · 2018-2019

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