

K182258 AquaShield System CO2Sep 21, 2018
31 days to decisionK182258 · Product code: **FEQ** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k182258/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pump, Air, Non-manual, For Endoscope (FEQ)
Date received	Aug 21, 2018
Decision date	Sep 21, 2018
Days to decision	31 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement
Other names	AquaShield System CO2 - PENTAX ; AquaShield System CO2 - Fujifilm

APPLICANT

Company	United States Endoscopy Group, Inc.
Location	Mentor, OH, US
Contact	Carroll L. Martin
510(k) history	94 submissions · 92 cleared · 1991-2020

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