

**K163424 AquaShield System - PENTAX, AquaShield System
CO2 - PENTAX, AquaShield System CO2 - FUJINON**Jan 4, 2017
29 days to decisionK163424 · Product code: FEQ · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k163424/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pump, Air, Non-manual, For Endoscope (FEQ)
Date received	Dec 6, 2016
Decision date	Jan 4, 2017
Days to decision	29 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	United State Endoscopy Group, Inc.
Location	Mentor, OH, US
Contact	Ganga Kolli
510(k) history	1 submissions · 1 cleared · 2017-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k163424/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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