

K161445 PerfIC Cath Gel S, PerfIC Cath Gel C, PerfIC Cath Hydro S, PerfIC Cath Hydro CAug 16, 2016
83 days to decisionK161445 · Product code: **EZD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k161445/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Straight (EZD)
Date received	May 25, 2016
Decision date	Aug 16, 2016
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Adapta Medical, Inc.
Location	Denver, CO, US
Contact	Adrian Elfe
510(k) history	2 submissions · 2 cleared · 2011-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161445/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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