

K180738 COMPACTCATH Lubricated Intermittent Urinary Catheter and OneCath Intermittent Urinary CatheterJun 14, 2018
84 days to decisionK180738 · Product code: **EZD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k180738/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Straight (EZD)
Date received	Mar 22, 2018
Decision date	Jun 14, 2018
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Compactcath, Inc.
Location	Lutsen, MN, US
Contact	Naama S. Breckler
510(k) history	3 submissions · 3 cleared · 2014-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180738/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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