FDA 510(k) Premarket Notification

K132619 CLASSIC INTERMITTENT CATHETER

CLEARED

Oct 11, 2013
51 days to decision

K132619 · Product code: **EZD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k132619/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	Aug 21, 2013
Decision date	Oct 11, 2013
Days to decision	51 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Flexicare Medical, Ltd.**
Location	Somerset, GB
Contact	CHRISTOPHER WATKINS
510(k) history	7 submissions · 7 cleared · 1995-2015

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k132619/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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