FDA 510(k) Premarket Notification

K141355 VOLUMETRIC INCENTIVE SPIROMETER

CLEARED

Sep 3, 2014
103 days to decision

K141355 · Product code: **BWF** · Anesthesiology
Source: https://www.510kdatabase.net/k141355/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Therapeutic (incentive) (BWF)
Date received	May 23, 2014
Decision date	Sep 3, 2014
Days to decision	103 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Besmed Health Business Corporation**
Location	New Taipei City, TW
Contact	PAUL DRYDEN
510(k) history	1 submissions · 1 cleared · 2014-2014

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k141355/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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