

K192584 BEACON Caresystem Model 00002144Dec 18, 2019
90 days to decisionK192584 · Product code: **BZK** · Anesthesiology
Source: <https://www.510kdatabase.net/k192584/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Monitoring (w/wo Alarm) (BZK)
Date received	Sep 19, 2019
Decision date	Dec 18, 2019
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mermaid Care A/S
Location	Norresundby, DK
Contact	Claus Lindholt
510(k) history	1 submissions · 1 cleared · 2019-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192584/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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