

K180079 Hill-Rom Vitals Monitoring System powered by EarlySense: Sensor Packs (different #), Hill-Rom Vitals Monitoring System powered by EarlySense: Sensor Activation

May 7, 2018
117 days to decision

K180079 · Product code: **BZQ** · Anesthesiology
Source: <https://www.510kdatabase.net/k180079/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Breathing Frequency (BZQ)
Date received	Jan 10, 2018
Decision date	May 7, 2018
Days to decision	117 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hill-Rom, Inc.
Location	Batesville, TN, US
Contact	Sarah Marie Fitzgerald
Website	http://www.hill-rom.com
510(k) history	33 submissions · 33 cleared · 1986-2021

Hill-Rom, Inc. is a global medical device manufacturer specializing in hospital care equipment and patient handling solutions. The company operates with a manufacturing facility in Batesville, Indiana, and serves healthcare providers across multiple care settings including hospitals, surgical centers, and home healthcare environments. Hill-Rom has received FDA 510(k) clearances from total submissions since its first clearance in 1986. The company's regulatory portfolio focuses on General Hospital devices, including patient beds, stretchers, warming systems, and fluid mana...