

K864261 MODEL 3500 INFANT RESPIRATION & HEART RATE MONITORMar 27, 1987
149 days to decisionK864261 · Product code: **BZQ** · Anesthesiology
Source: <https://www.510kdatabase.net/k864261/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Breathing Frequency (BZQ)
Date received	Oct 29, 1986
Decision date	Mar 27, 1987
Days to decision	149 days
Third-party review	No

APPLICANT

Company	Bio-Dyne, Inc.
Location	Milford, CT, US
Contact	JAMES WALLS
510(k) history	3 submissions · 3 cleared · 1987-1990

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