FDA 510(k) Premarket Notification

K883158 RESPIRATORY AIRWAY TUBE MONITOR (RATM)

CLEARED

Mar 6, 1989
223 days to decision

K883158 · Product code: **BZQ** · Anesthesiology
Source: https://www.510kdatabase.net/k883158/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Breathing Frequency (BZQ)
Date received	Jul 26, 1988
Decision date	Mar 6, 1989
Days to decision	223 days
Third-party review	No

APPLICANT

Company	**Vascucare, Inc.**
Location	Orangeburg, NY, US
Contact	SUZANNE LETSO
510(k) history	3 submissions · 3 cleared · 1988-1989

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k883158/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026