FDA 510(k) Premarket Notification

K921309 MODEL 508 PATIENT MONITOR

CLEARED

Dec 17, 1993
647 days to decision

K921309 · Product code: **BTY** · Anesthesiology
Source: https://www.510kdatabase.net/k921309/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calculator, Predicted Values, Pulmonary Function (BTY)
Date received	Mar 10, 1992
Decision date	Dec 17, 1993
Days to decision	647 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Criticare Systems, Inc.**
Location	Milwaukee, WI, US
Contact	ALEX KAPLAN
Website	http://www.csiusa.com/?home
510(k) history	22 submissions · 22 cleared · 1986-2010

Criticare Systems, Inc. is an international medical device company headquartered in Warwick, RI, with a manufacturing facility in Milwaukee, US. The company develops and distributes patient monitoring devices and anesthetic gas monitoring systems. Products address safety and monitoring needs in anesthesia, critical care, respiratory care, transport, and outpatient care environments. Criticare Systems received FDA 510(k) clearances from total submissions between 1986 and 2010. The company's cleared devices focus on cardiovascular monitoring, including vital signs monitors,...