FDA 510(k) Premarket Notification

K022435 507EL VITAL SIGNS MONITOR

CLEARED

Aug 14, 2002
20 days to decision

K022435 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k022435/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Jul 25, 2002
Decision date	Aug 14, 2002
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

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,...