FDA 510(k) Premarket Notification

CLEARED

K030613 VITAL SIGNS MONITOR W/ARRHYTHMIA DETECTION AND ST ANALYSIS, MODEL 8100

Apr 17, 2003
50 days to decision

K030613 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k030613/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Feb 26, 2003
Decision date	Apr 17, 2003
Days to decision	50 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,...