FDA 510(k) Premarket Notification

K884643 1100 VITAL SIGNS MONITOR

CLEARED

Oct 30, 1989
357 days to decision

K884643 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k884643/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Nov 7, 1988
Decision date	Oct 30, 1989
Days to decision	357 days
Third-party review	No

APPLICANT

Company	**Criticare Systems, Inc.**
Location	Milwaukee, WI, US
Contact	DER RUHR
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,...