

K910852 507 NON-INVASIVE VITAL SIGNS MONITORJul 30, 1991
153 days to decisionK910852 · Product code: **DRT** · Cardiovascular
Source: <https://www.510kdatabase.net/k910852/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Feb 27, 1991
Decision date	Jul 30, 1991
Days to decision	153 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,...

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