

K864613 502 OXYGEN SATURATION MONITORMar 4, 1987
100 days to decisionK864613 · Product code: **DQA** · Anesthesiology
Source: <https://www.510kdatabase.net/k864613/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Nov 24, 1986
Decision date	Mar 4, 1987
Days to decision	100 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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