FDA 510(k) Premarket Notification

K911124 503 PULSE OXIMETER

CLEARED

Jun 7, 1991
87 days to decision

K911124 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k911124/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Mar 12, 1991
Decision date	Jun 7, 1991
Days to decision	87 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,...