FDA 510(k) Premarket Notification

K875298 502-US PULSE OXIMETER

CLEARED

Mar 7, 1988
68 days to decision

K875298 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k875298/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Dec 30, 1987
Decision date	Mar 7, 1988
Days to decision	68 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,...