

**K944860 SCHOLAR PATIENT MONITOR**Jun 20, 1995  
260 days to decisionK944860 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k944860/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Oct 3, 1994
Decision date	Jun 20, 1995
Days to decision	260 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Criticare Systems, Inc.</b>
Location	Milwaukee, WI, US
Contact	ALEX KAPLAN
Website	<a href="http://www.csiusa.com/?home">http://www.csiusa.com/?home</a>
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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