

**K000168 CS/3 CRITICAL CARE MONITOR WITH S-ICU99(A)**Apr 13, 2000  
84 days to decisionK000168 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k000168/>**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	Jan 20, 2000
Decision date	Apr 13, 2000
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Datex-Ohmeda</b>
Location	Tewksbury, MA, US
Contact	JOEL KENT
510(k) history	41 submissions · 41 cleared · 2000-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k000168/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 24, 2026