

K002158 S/5 COMPACT CRITICAL CARE MONITOR WITH S-00C03 OR S-00C04 SOFTWARE

Sep 6, 2000
51 days to decision

K002158 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k002158/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jul 17, 2000
Decision date	Sep 6, 2000
Days to decision	51 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Datex-Ohmeda, Inc.
Location	Madison, WI, US
Contact	JOEL KENT
510(k) history	60 submissions · 60 cleared · 1998-2025

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Device record: <https://www.510kdatabase.net/k002158/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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