

K021376 DATEX-OHMEDA S/5 CRITICAL CARE MONITOR WITH L-ICU02 AND L-ICU02A SOFTWAREJul 24, 2002
84 days to decisionK021376 · Product code: **DSI** · Cardiovascular
Source: <https://www.510kdatabase.net/k021376/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	May 1, 2002
Decision date	Jul 24, 2002
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k021376/> Data sourced from FDA 510(k) public records (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. - Generated May 24, 2026