

K043276 DATEX-OHMEDA S/5TM FM WITH L-FICU04 AND L-FICU04A SOFTWARE AND N-FCREC MODULE

Dec 23, 2004
27 days to decision

K043276 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k043276/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Nov 26, 2004
Decision date	Dec 23, 2004
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k043276/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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