FDA 510(k) Premarket Notification

K993608 DATEX-OHMEDA NE12STPR MODULE (MODEL FAMILY M-NE12STPR)

CLEARED

Apr 13, 2000
171 days to decision

K993608 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k993608/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Oct 25, 1999
Decision date	Apr 13, 2000
Days to decision	171 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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