FDA 510(k) Premarket Notification

K000882 DATEX-OHMEDA CS/3 TELEMETRY SYSTEM

CLEARED

Jun 5, 2000
77 days to decision

K000882 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k000882/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Mar 20, 2000
Decision date	Jun 5, 2000
Days to decision	77 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