FDA 510(k) Premarket Notification

K031781 DATEX-OHMEDA PRESTN MODULE, (MODEL FAMILY M-PRESTN) AND ACCESSORIES

CLEARED

Jun 25, 2003
15 days to decision

K031781 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k031781/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jun 10, 2003
Decision date	Jun 25, 2003
Days to decision	15 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