FDA 510(k) Premarket Notification

CLEARED

K041772 DATEX-OHMEDA PRESTN.01 MODULE (MODEL FAMILY M-PRESTN.01) AND ACCESSORIES

Jul 28, 2004
27 days to decision

K041772 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k041772/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jul 1, 2004
Decision date	Jul 28, 2004
Days to decision	27 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