FDA 510(k) Premarket Notification

K040395 CENTRAL TELEMETRY SYSTEM, MODEL WEP-4200A SERIES

CLEARED

Jun 1, 2004
105 days to decision

K040395 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k040395/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Feb 17, 2004
Decision date	Jun 1, 2004
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Nihon Kohden America, Inc.**
Location	Foothill Ranch, CA, US
Contact	SERRAH NAMINI
510(k) history	166 submissions · 163 cleared · 1979-2012