FDA 510(k) Premarket Notification

K945385 VITALMAX 800 PLUS/VITALMAX 810 PLUS/MINIPACK 300

CLEARED

Jan 31, 1995
89 days to decision

K945385 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k945385/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Nov 3, 1994
Decision date	Jan 31, 1995
Days to decision	89 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Pace Tech, Inc.**
Location	Clearwater, FL, US
Contact	B ILGUTAY
510(k) history	18 submissions · 18 cleared · 1988-1996