FDA 510(k) Premarket Notification

K011000 TRAM 2001 MODULE

CLEARED

Jun 29, 2001
87 days to decision

K011000 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k011000/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Apr 3, 2001
Decision date	Jun 29, 2001
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**General Electric Medical Systems Information Techn**
Location	Sugarland, TX, US
Contact	KAREN WEBB
510(k) history	33 submissions · 33 cleared · 1999-2002