FDA 510(k) Premarket Notification

K924575 ATLANTIS GUI

CLEARED

Mar 4, 1993
175 days to decision

K924575 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k924575/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Sep 10, 1992
Decision date	Mar 4, 1993
Days to decision	175 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Hospitronics**
Location	France, FR
Contact	MONTEJO
510(k) history	1 submissions · 1 cleared · 1993-1993