FDA 510(k) Premarket Notification

K032369 MODIFICATION TO: APEXPRO TELEMETRY SYSTEM

CLEARED

Aug 15, 2003
14 days to decision

K032369 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k032369/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Aug 1, 2003
Decision date	Aug 15, 2003
Days to decision	14 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ge Medical Systems Information Technologies**
Location	Mchenry, IL, US
Contact	DIANA M THORSON
510(k) history	136 submissions · 132 cleared · 1978-2012