FDA 510(k) Premarket Notification

K934644 K3 SYSTEM

CLEARED

Nov 1, 1994
398 days to decision

K934644 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k934644/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Sep 29, 1993
Decision date	Nov 1, 1994
Days to decision	398 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Astro-Med, Inc.**
Location	West Warwick, RI, US
Contact	MICHAEL SULLIVAN
510(k) history	13 submissions · 13 cleared · 1989-2008