FDA 510(k) Premarket Notification

K911616 HORIZON XL

CLEARED

Jul 10, 1991
90 days to decision

K911616 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k911616/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Apr 11, 1991
Decision date	Jul 10, 1991
Days to decision	90 days
Third-party review	No

APPLICANT

Company	**Mennen Medical, Inc.**
Location	Clarence, NY, US
Contact	RICHARD G WHITEHEAD
510(k) history	34 submissions · 34 cleared · 1985-2004