FDA 510(k) Premarket Notification

K911611 SYSTEM ATHENA, MODIFICATION

CLEARED

Feb 5, 1993
668 days to decision

K911611 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k911611/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Apr 9, 1991
Decision date	Feb 5, 1993
Days to decision	668 days
Third-party review	No

APPLICANT

Company	**S & W Medico Teknik**
Location	Walker, MI, US
Contact	MORTEN NIELSON
510(k) history	46 submissions · 46 cleared · 1984-1995