FDA 510(k) Premarket Notification

K894699 TYPE 9140 (SYSTEM ATHENA)

CLEARED

Oct 2, 1989
70 days to decision

K894699 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k894699/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Jul 24, 1989
Decision date	Oct 2, 1989
Days to decision	70 days
Third-party review	No

APPLICANT

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