FDA 510(k) Premarket Notification

K900366 ARRHYTHMIA 9215

CLEARED

Apr 26, 1991
455 days to decision

K900366 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k900366/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Jan 26, 1990
Decision date	Apr 26, 1991
Days to decision	455 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