FDA 510(k) Premarket Notification

K922027 AMBULATORY (HOLTER) RECORDING, MODIFICATION

CLEARED

Feb 17, 1993
328 days to decision

K922027 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k922027/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Mar 26, 1992
Decision date	Feb 17, 1993
Days to decision	328 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Biosensor Corp.**
Location	Walker, MI, US
Contact	STEVE SPRINGROSE
510(k) history	10 submissions · 10 cleared · 1983-1999