FDA 510(k) Premarket Notification

K895266 AMBULATORY (HOLTER) RECORDING SYSTEM - MODIFIED

CLEARED

Jan 26, 1990
156 days to decision

K895266 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k895266/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Aug 23, 1989
Decision date	Jan 26, 1990
Days to decision	156 days
Third-party review	No

APPLICANT

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