FDA 510(k) Premarket Notification

K780343 ARRHYTHMIA TREND ENHANCEMENT

CLEARED

Apr 18, 1978
47 days to decision

K780343 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k780343/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Mar 2, 1978
Decision date	Apr 18, 1978
Days to decision	47 days
Third-party review	No

APPLICANT

Company	**American Optical Corp.**
Location	Mchenry, IL, US
510(k) history	35 submissions · 35 cleared · 1976-1995