FDA 510(k) Premarket Notification

K012428 MODIFICATION TO: LIFEPAK 500 AUTOMATED EXTERNAL DEFIBRILLATOR

CLEARED

Sep 28, 2001
59 days to decision

K012428 · Product code: **MKJ** · Cardiovascular
Source: https://www.510kdatabase.net/k012428/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Jul 31, 2001
Decision date	Sep 28, 2001
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic Physio-Control Corp.**
Location	Redmond, WA, US
Contact	SHERRI L POCOCK
510(k) history	8 submissions · 6 cleared · 2001-2004