FDA 510(k) Premarket Notification

K010214 FIRSTSAVE BIPHASIC MODEL #9200 AND 9210

CLEARED

Feb 22, 2001
30 days to decision

K010214 · Product code: **MKJ** · Cardiovascular
Source: https://www.510kdatabase.net/k010214/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Jan 23, 2001
Decision date	Feb 22, 2001
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Survivalink Corp.**
Location	Minnetonka, MN, US
Contact	Sew-Wah Tay
510(k) history	7 submissions · 5 cleared · 1995-2002