FDA 510(k) Premarket Notification

# K781678 DEFIBRILLATOR, MARK II

**CLEARED**

Dec 12, 1978
71 days to decision

K781678 · Product code: **LDD** · Cardiovascular
Source: https://www.510kdatabase.net/k781678/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dc-defibrillator, Low-energy, (including Paddles) (LDD) |
| Date received | Oct 2, 1978 |
| Decision date | Dec 12, 1978 |
| Days to decision | 71 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Ipco Corp.** |
| Location | Mchenry, IL, US |
| Website | https://www.ipco.com |
| 510(k) history | 23 submissions · 23 cleared · 1976-1987 |

Ipco Corp. is an industrial equipment manufacturer based in McHenry, US, specializing in production process solutions including steel belts and conveyor systems. The company has received FDA 510(k) clearances from total submissions, spanning from 1976 to 1987. Ipco Corp. maintained a successful regulatory track record across dental devices, obstetrics and gynecology products, and gastroenterology and urology devices. This historical record reflects the company's diverse medical device portfolio during its active regulatory period. Ipco Corp. is inactive and should be trea...