FDA 510(k) Premarket Notification

# K903437 DISPOS ACCESS EXTERNAL CARDIAC PACEMAKER

**CLEARED**

Nov 16, 1990
108 days to decision

K903437 · Product code: **DRO** · Cardiovascular
Source: https://www.510kdatabase.net/k903437/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Pacemaker, Cardiac, External Transcutaneous (non-invasive) (DRO) |
| Date received | Jul 31, 1990 |
| Decision date | Nov 16, 1990 |
| Days to decision | 108 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Keller Medical Specialties Products, Inc.** |
| Location | Antioch, IL, US |
| Contact | JAY KELLER |
| 510(k) history | 6 submissions · 6 cleared · 1990-1999 |