FDA 510(k) Premarket Notification

# K874366 ENCOR BIPOLAR ACT/FIXA LEAD W/POR SUR ELE #329-201

**CLEARED**

Jun 16, 1988
237 days to decision

K874366 · Product code: **DTB** · Cardiovascular
Source: https://www.510kdatabase.net/k874366/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Permanent Pacemaker Electrode (DTB) |
| Date received | Oct 23, 1987 |
| Decision date | Jun 16, 1988 |
| Days to decision | 237 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Cordis Leads, Inc.** |
| Location | Suffield, CT, US |
| Contact | WILLIAM C NEALON |
| 510(k) history | 4 submissions · 4 cleared · 1988-1988 |