FDA 510(k) Premarket Notification

# K792199 UNIFOCAL 2-UNIPOLAR & BIPOLAR

**CLEARED**

Nov 27, 1979
26 days to decision

K792199 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k792199/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implantable Pacemaker Pulse-generator (DXY) |
| Date received | Nov 1, 1979 |
| Decision date | Nov 27, 1979 |
| Days to decision | 26 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **American Pacemaker Corp.** |
| Location | Mchenry, IL, US |
| 510(k) history | 14 submissions · 14 cleared · 1977-1982 |