

K952364 OPUS PACEMAKERS (MODELS 4001, 4003, 4004, 4023, 4024)Sep 1, 1995
123 days to decisionK952364 · Product code: **DXY** · Cardiovascular
Source: <https://www.510kdatabase.net/k952364/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent - ST |
| Submission type | Traditional |
| Device classification | Implantable Pacemaker Pulse-generator (DXY) |
| Date received | May 1, 1995 |
| Decision date | Sep 1, 1995 |
| Days to decision | 123 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Ela Medical, Inc. |
| Location | Mchenry, IL, US |
| Contact | CATHY GOBLE |
| 510(k) history | 43 submissions · 36 cleared · 1979-2004 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k952364/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 3, 2026