

**K812358 MODEL 325T PROGRAMMABLE PULSE GENERATOR**Oct 29, 1981  
70 days to decisionK812358 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k812358/>**SUBMISSION DETAILS**

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|                       |                                             |
|-----------------------|---------------------------------------------|
| Decision              | Substantially Equivalent (Cleared)          |
| Submission type       | Traditional                                 |
| Device classification | Implantable Pacemaker Pulse-generator (DXY) |
| Date received         | Aug 20, 1981                                |
| Decision date         | Oct 29, 1981                                |
| Days to decision      | 70 days                                     |
| Third-party review    | No                                          |

**APPLICANT**

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|----------------|-----------------------------------------|
| Company        | <b>Cook Pacemaker Corp.</b>             |
| Location       | Mchenry, IL, US                         |
| 510(k) history | 34 submissions · 31 cleared · 1981-1997 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k812358/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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