

**K810121 UNIFOCAL 3**Feb 23, 1981  
35 days to decisionK810121 · Product code: **DXY** · Radiology  
Source: <https://www.510kdatabase.net/k810121/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)          |
| Submission type       | Traditional                                 |
| Device classification | Implantable Pacemaker Pulse-generator (DXY) |
| Date received         | Jan 19, 1981                                |
| Decision date         | Feb 23, 1981                                |
| Days to decision      | 35 days                                     |
| Third-party review    | No  |

**APPLICANT**

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

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

Device record: <https://www.510kdatabase.net/k810121/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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