

**K791225 BJORK-SHILEY AORTIC GRAFT VALVE PROSTH**Aug 10, 1979  
38 days to decisionK791225 · Product code: **DXY** · CardiovascularSource: <https://www.510kdatabase.net/k791225/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jul 3, 1979
Decision date	Aug 10, 1979
Days to decision	38 days
Third-party review	No

**APPLICANT**

---

Company	<b>Shiley, Inc.</b>
Location	Mchenry, IL, US
510(k) history	174 submissions · 174 cleared · 1976-1993

---

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

Device record: <https://www.510kdatabase.net/k791225/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026