FDA 510(k) Premarket Notification

K791225 BJORK-SHILEY AORTIC GRAFT VALVE PROSTH

CLEARED

Aug 10, 1979
38 days to decision

K791225 · Product code: **DXY** · Cardiovascular
Source: 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	**Shiley, Inc.**
Location	Mchenry, IL, US
510(k) history	174 submissions · 174 cleared · 1976-1993