CLEARED

K800379 BIFOCAL 2 8200 SERIES (A,B C,D)

Sep 26, 1980
217 days to decision

K800379 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k800379/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Feb 22, 1980
Decision date	Sep 26, 1980
Days to decision	217 days
Third-party review	No

APPLICANT

Company	**American Pacemaker Corp.**
Location	Mchenry, IL, US
510(k) history	14 submissions · 14 cleared · 1977-1982