FDA 510(k) Premarket Notification

K810121 UNIFOCAL 3

CLEARED

Feb 23, 1981
35 days to decision

K810121 · Product code: **DXY** · Radiology
Source: https://www.510kdatabase.net/k810121/

SUBMISSION DETAILS

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

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