FDA 510(k) Premarket Notification

K781973 CARDIOPHONE

CLEARED

Mar 21, 1979
114 days to decision

K781973 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k781973/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Nov 27, 1978
Decision date	Mar 21, 1979
Days to decision	114 days
Third-party review	No

APPLICANT

Company	**North American Motronic**
Location	Mchenry, IL, US
510(k) history	1 submissions · 1 cleared · 1979-1979