FDA 510(k) Premarket Notification

K810808 CORATOMIC MODEL OVALITH-920

CLEARED

May 15, 1981
52 days to decision

K810808 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k810808/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Mar 24, 1981
Decision date	May 15, 1981
Days to decision	52 days
Third-party review	No

APPLICANT

Company	**Coratomic, Inc.**
Location	Mchenry, IL, US
510(k) history	15 submissions · 14 cleared · 1976-1986