FDA 510(k) Premarket Notification

K810493 TYPE N ENDOCARDIAL LEAD

CLEARED

Mar 20, 1981
24 days to decision

K810493 · Product code: **DTB** · Cardiovascular
Source: https://www.510kdatabase.net/k810493/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Feb 24, 1981
Decision date	Mar 20, 1981
Days to decision	24 days
Third-party review	No

APPLICANT

Company	**Biotronik Sales, Inc.**
Location	Mchenry, IL, US
510(k) history	41 submissions · 41 cleared · 1980-1988