FDA 510(k) Premarket Notification

K810494 TYPE FH ENDOCARDIAL LEAD

CLEARED

Aug 7, 1981
164 days to decision

K810494 · Product code: **DTB** · Cardiovascular
Source: https://www.510kdatabase.net/k810494/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Feb 24, 1981
Decision date	Aug 7, 1981
Days to decision	164 days
Third-party review	No

APPLICANT

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