FDA 510(k) Premarket Notification

K000763 PX 53/15-BP, MODEL 130 050 AND PX 60/15-BP, MODEL 130 051

CLEARED

Apr 6, 2000
28 days to decision

K000763 · Product code: **DTB** · Cardiovascular
Source: https://www.510kdatabase.net/k000763/

SUBMISSION DETAILS

Decision	Substantially Equivalent - ST
Submission type	Special
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Mar 9, 2000
Decision date	Apr 6, 2000
Days to decision	28 days
Third-party review	No

APPLICANT

Company	**Biotronik, GmbH & Co.**
Location	Lake Oswego, OR, US
Contact	Jon Brumbaugh
510(k) history	18 submissions · 17 cleared · 1989-2000