CLEARED

K980869 SYNOX SX 53-BP, SX 60-BP, SX 45-JBP, SX 53-JBP , MODELS 120 444, 119 684, 120 438 AND 120 143

Sep 10, 1998
188 days to decision

K980869 · Product code: **DTB** · Cardiovascular
Source: https://www.510kdatabase.net/k980869/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Mar 6, 1998
Decision date	Sep 10, 1998
Days to decision	188 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biotronik, Inc.**
Location	Lake Oswego, OR, US
Contact	DAVID MAKANANI
Website	https://www.biotronik.com
510(k) history	85 submissions · 67 cleared · 1994-2026

Biotronik, Inc. designs and manufactures advanced active implants for cardiac rhythm management, monitoring, and electrophysiology. The company operates with a manufacturing facility in Lake Oswego, Oregon, and serves patients globally through innovative cardiovascular solutions. Biotronik has received FDA 510(k) clearances from total submissions since its first clearance in 1994. The company specializes exclusively in cardiovascular devices, including pacing systems, implantable cardioverter defibrillators, cardiac resynchronization therapies, and electrophysiology cathe...