CLEARED

K981083 RETROX RX 53-BP, RETROX RX 60-BP, RETROX RX 45-JBP, RETROX RX 53-JBP MODEL NUMBERS 124 396, 124 397, 124 395, 124 000

Jul 22, 1998
120 days to decision

K981083 · Product code: **DTB** · Cardiovascular
Source: https://www.510kdatabase.net/k981083/

SUBMISSION DETAILS

Decision	Substantially Equivalent - ST
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Mar 24, 1998
Decision date	Jul 22, 1998
Days to decision	120 days
Third-party review	No

APPLICANT

Company	**Biotronik, Inc.**
Location	Lake Oswego, OR, US
Contact	LAUREN L FOOTE CHRISTENSEN
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...