FDA 510(k) Premarket Notification

K896443 MYOPORE(TM) UNIPOLAR MODELS 1117 & 1118 PACE LEADS

CLEARED

Dec 20, 1989
41 days to decision

K896443 · Product code: **DTB** · Cardiovascular
Source: https://www.510kdatabase.net/k896443/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Nov 9, 1989
Decision date	Dec 20, 1989
Days to decision	41 days
Third-party review	No

APPLICANT

Company	**Possis Medical, Inc.**
Location	Walker, MI, US
Contact	ROBERT J SCOTT
510(k) history	34 submissions · 34 cleared · 1983-2014