FDA 510(k) Premarket Notification

K012460 MODEL 6495 BIPOLAR TEMPORARY MYOCARDIAL PACING LEAD

CLEARED

Aug 14, 2001
13 days to decision

K012460 · Product code: **LDF** · Cardiovascular
Source: https://www.510kdatabase.net/k012460/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrode, Pacemaker, Temporary (LDF)
Date received	Aug 1, 2001
Decision date	Aug 14, 2001
Days to decision	13 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic Vascular**
Location	Walker, MI, US
Contact	TINA BENOIT
510(k) history	475 submissions · 453 cleared · 1977-2023