FDA 510(k) Premarket Notification

K852119 TEMPORARY PACEMAKER GROUND WIRE

CLEARED

Sep 15, 1985
123 days to decision

K852119 · Product code: **DTB** · Cardiovascular
Source: https://www.510kdatabase.net/k852119/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	May 15, 1985
Decision date	Sep 15, 1985
Days to decision	123 days
Third-party review	No

APPLICANT

Company	**Scholten Surgical Instruments, Inc.**
Location	Redwood City, CA, US
Contact	JAKE(JACOBUS) SCHOLT
510(k) history	8 submissions · 8 cleared · 1985-2007