FDA 510(k) Premarket Notification

K173923 Temporary Cardiac Pacing Wire

CLEARED

Aug 2, 2018
219 days to decision

K173923 · Product code: **LDF** · Cardiovascular
Source: https://www.510kdatabase.net/k173923/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Pacemaker, Temporary (LDF)
Date received	Dec 26, 2017
Decision date	Aug 2, 2018
Days to decision	219 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ethicon, Inc.**
Location	Raritan, NJ, US
Contact	Joice Pappan
Website	https://www.jnjmedtech.com
510(k) history	203 submissions · 196 cleared · 1976-2026

Ethicon, Inc. is a subsidiary of Johnson & Johnson specializing in surgical sutures and wound closure devices. The company is headquartered in Raritan, United States. Ethicon has received FDA 510(k) clearances from total submissions since 1976. The company's regulatory focus centers on General & Plastic Surgery devices, which represent the majority of its cleared submissions. The latest FDA 510(k) clearance was granted in 2026, demonstrating continued regulatory activity. Ethicon has manufactured surgical sutures and wound closure technologies since 1887. The company hold...