FDA 510(k) Premarket Notification

K813138 ETHICON* TEMP. CARDIAC PACING WIRE

CLEARED

Dec 10, 1981
34 days to decision

K813138 · Product code: **LDF** · Cardiovascular
Source: https://www.510kdatabase.net/k813138/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Pacemaker, Temporary (LDF)
Date received	Nov 6, 1981
Decision date	Dec 10, 1981
Days to decision	34 days
Third-party review	No

APPLICANT

Company	**Ethicon, Inc.**
Location	Raritan, NJ, US
Website	https://www.jnjmedtech.com
510(k) history	204 submissions · 197 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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k813138/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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