

K861409 SYNCARE TEMPORARY CARDIAC PACING WIREMay 5, 1986
20 days to decisionK861409 · Product code: **LDF** · CardiovascularSource: <https://www.510kdatabase.net/k861409/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Pacemaker, Temporary (LDF)
Date received	Apr 15, 1986
Decision date	May 5, 1986
Days to decision	20 days
Third-party review	No

APPLICANT

Company	Gyneco, Inc.
Location	Mchenry, IL, US
Contact	BUDAY, PH.D.
510(k) history	5 submissions · 5 cleared · 1984-1986

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k861409/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 30, 2026