

**K043513 STERILMED REPROCESSED DEFLECTABLE
ELECTROPHYSIOLOGY DIAGNOSTIC CATHETER**Mar 1, 2005
71 days to decisionK043513 · Product code: **NLH** · Cardiovascular
Source: <https://www.510kdatabase.net/k043513/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Recording, Electrode, Reprocessed (NLH)
Date received	Dec 20, 2004
Decision date	Mar 1, 2005
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sterilmed, Inc.
Location	Plymouth, MN, US
Contact	BRUCE R LESTER
510(k) history	64 submissions · 64 cleared · 2001-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k043513/> 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 May 19, 2026