

**K883984 HEMORX COLD PACK**Dec 22, 1988  
93 days to decisionK883984 · Product code: **LKX** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k883984/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Thermal, Hemorrhoids (LKX)
Date received	Sep 20, 1988
Decision date	Dec 22, 1988
Days to decision	93 days
Third-party review	No

**APPLICANT**

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Company	<b>Bio-Dyne, Inc.</b>
Location	Milford, CT, US
Contact	RICHARD A CARSILLO
510(k) history	3 submissions · 3 cleared · 1987-1990

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k883984/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026