

K981428 ANU ICEJul 7, 1998
78 days to decisionK981428 · Product code: **LKX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k981428/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Thermal, Hemorrhoids (LKX)
Date received	Apr 20, 1998
Decision date	Jul 7, 1998
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cryotherapy Pain Relief Products, Inc.
Location	Pembroke Pines, FL, US
Contact	JORGE CABALLERO
510(k) history	1 submissions · 1 cleared · 1998-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k981428/> 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 July 1, 2026