

K943497 CONTRAST 7000 THERAPY SYSTEMJun 7, 1995
323 days to decisionK943497 · Product code: **ILO** · Physical Medicine
Source: <https://www.510kdatabase.net/k943497/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pack, Hot Or Cold, Water Circulating (ILO)
Date received	Jul 19, 1994
Decision date	Jun 7, 1995
Days to decision	323 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Burke Neutech, Inc.
Location	Largo, FL, US
Contact	ROBERT E BURKE
510(k) history	7 submissions · 6 cleared · 1993-1996

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k943497/> 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 29, 2026