

K940160 TS1000 PORTABLE DISPOSABLE COLD THERAPY SYSTEMMay 27, 1994
135 days to decisionK940160 · Product code: **ILO** · Physical Medicine
Source: <https://www.510kdatabase.net/k940160/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pack, Hot Or Cold, Water Circulating (ILO)
Date received	Jan 12, 1994
Decision date	May 27, 1994
Days to decision	135 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/k940160/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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