FDA 510(k) Premarket Notification

K935010 WALLACH ULTRA FREEZE

CLEARED

Feb 9, 1994
112 days to decision

K935010 · Product code: **GEH** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k935010/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Oct 20, 1993
Decision date	Feb 9, 1994
Days to decision	112 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Wallach Surgical Devices, Inc.**
Location	Walker, MI, US
Contact	RAYMOND A WILEY
510(k) history	27 submissions · 27 cleared · 1981-2002

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k935010/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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