

**K945055 HARKEN ASSURE SELF-SEAL STERILIZATION
POUCH**Dec 14, 1994
61 days to decisionK945055 · Product code: **KCT** · General Hospital
Source: <https://www.510kdatabase.net/k945055/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (KCT)
Date received	Oct 14, 1994
Decision date	Dec 14, 1994
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Harken Products, Inc.
Location	Irwindall, CA, US
Contact	CHARLES R HARDER
510(k) history	1 submissions · 1 cleared · 1994-1994

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