

K950597 CORE-RESISTANT HUBER INFUSION SET WITH Y-SITEJul 26, 1995
167 days to decisionK950597 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k950597/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Feb 9, 1995
Decision date	Jul 26, 1995
Days to decision	167 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Distronic Sterile Products, Inc.
Location	Portsmouth, NH, US
Contact	JOYCE MCDUGALL
510(k) history	8 submissions · 8 cleared · 1995-1996

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k950597/>. 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 6, 2026