

K080645 STD MED PRIMO PORT POLYMay 2, 2008
57 days to decisionK080645 · Product code: **LJT** · General Hospital
Source: <https://www.510kdatabase.net/k080645/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Port & Catheter, Implanted, Subcutaneous, Intravascular (LJT)
Date received	Mar 6, 2008
Decision date	May 2, 2008
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Std Med, Inc.
Location	Ayer, MA, US
Contact	PAMELA PAPINEAU
510(k) history	2 submissions · 2 cleared · 2007-2008

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080645/> 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 25, 2026