

K953024 LINDNER/GOLOMB SP INTRODUCING SOUNDAug 18, 1995
50 days to decisionK953024 · Product code: **KOB** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k953024/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Suprapubic (and Accessories) (KOB)
Date received	Jun 29, 1995
Decision date	Aug 18, 1995
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cook Urological, Inc.
Location	Spencer, IN, US
Contact	TAMMY BACON
510(k) history	104 submissions · 102 cleared · 1986-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k953024/> 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 19, 2026