

K935531 OP-FLEX SUMP SUCTION SET WITH DIFFUSER TIPMay 5, 1994
170 days to decisionK935531 · Product code: **GBX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k935531/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Irrigation (GBX)
Date received	Nov 16, 1993
Decision date	May 5, 1994
Days to decision	170 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Puritas Health Care, Inc.
Location	Brookfield, CT, US
Contact	THOMAS P DIMAIO
510(k) history	24 submissions · 22 cleared · 1991-1994

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k935531/> 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 May 26, 2026