

K935993 SURGICAL SPONGE X-RAY DETECTABLEFeb 2, 1994
51 days to decisionK935993 · Product code: **GDY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k935993/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gauze/sponge, Internal, X-ray Detectable (GDY)
Date received	Dec 13, 1993
Decision date	Feb 2, 1994
Days to decision	51 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Mcneil Healthcare, Inc.
Location	Waterford, CT, US
Contact	TIMOTHY D MCNEIL
510(k) history	19 submissions · 19 cleared · 1994-1994

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k935993/> 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