

K945606 TRIANGULAR SPONGESDec 28, 1994
43 days to decisionK945606 · Product code: **GDY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k945606/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gauze/sponge, Internal, X-ray Detectable (GDY)
Date received	Nov 15, 1994
Decision date	Dec 28, 1994
Days to decision	43 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Lorrex Health Products
Location	Secaucus, NJ, US
Contact	DAVID M PIERATOS
510(k) history	16 submissions · 16 cleared · 1993-1994

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k945606/> 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