

**K945553 ROUND STICK SPONGES, FLAT STICK SPONGES**Dec 28, 1994  
48 days to decisionK945553 · Product code: **GDY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k945553/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gauze/sponge, Internal, X-ray Detectable (GDY)
Date received	Nov 10, 1994
Decision date	Dec 28, 1994
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k945553/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 6, 2026