

K042811 VIVOSORB SHEET, MODEL FS01Nov 8, 2004
27 days to decisionK042811 · Product code: **FTL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k042811/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Oct 12, 2004
Decision date	Nov 8, 2004
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Polyganics B.V.,
Location	Groningen, NL
Contact	JAN NIEUWENHUIS
510(k) history	9 submissions · 9 cleared · 2003-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k042811/> 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 6, 2026