

**K051503 UGYTEX SUAL KNIT MESH**Aug 5, 2005  
59 days to decisionK051503 · Product code: **OTP** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k051503/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Pelvic Organ Prolapse, Transvaginally Placed (OTP)
Date received	Jun 7, 2005
Decision date	Aug 5, 2005
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sofradim Production</b>
Location	Ayer, MA, US
Contact	PAMELA PAPINEAU
510(k) history	42 submissions · 42 cleared · 1999-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k051503/> 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 June 29, 2026