

**K012949 URETEX SUP PUBOURETHRAL SLING**Oct 4, 2001  
30 days to decisionK012949 · Product code: **OTN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k012949/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic Or Transobturator (OTN)
Date received	Sep 4, 2001
Decision date	Oct 4, 2001
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Sofradim Production</b>
Location	Ayer, MA, US
Contact	MARY MCNAMARA-CULLINANE
510(k) history	41 submissions · 41 cleared · 1999-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012949/> 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 May 14, 2026