

**K041176 URETEX TO TRANS-OBTURATOR URETHRAL  
SUPPORT SYSTEM**May 17, 2004  
12 days to decisionK041176 · Product code: **OTN** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k041176/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic Or Transobturator (OTN)
Date received	May 5, 2004
Decision date	May 17, 2004
Days to decision	12 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k041176/>; 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