

K033691 SAFYRE VS AND SAFYRE TDec 19, 2003
25 days to decisionK033691 · Product code: **OTN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k033691/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic Or Transobturator (OTN)
Date received	Nov 24, 2003
Decision date	Dec 19, 2003
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Promedon
Location	Essex Junction, VT, US
Contact	DEBBIE IAMPIETRO
510(k) history	2 submissions · 2 cleared · 2002-2003

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