FDA 510(k) Premarket Notification

K012949 URETEX SUP PUBOURETHRAL SLING

CLEARED

Oct 4, 2001
30 days to decision

K012949 · Product code: **OTN** · Gastroenterology & Urology
Source: 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	**Sofradim Production**
Location	Ayer, MA, US
Contact	MARY MCNAMARA-CULLINANE
510(k) history	41 submissions · 41 cleared · 1999-2025