FDA 510(k) Premarket Notification

K020110 MODIFICATION TO TRELEX MESH SURGICAL MESH

CLEARED

Apr 3, 2002
82 days to decision

K020110 · Product code: **OTN** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k020110/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic Or Transobturator (OTN)
Date received	Jan 11, 2002
Decision date	Apr 3, 2002
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Boston Scientific**
Location	San Jose, CA, US
Contact	DONNA M GARDNER
Website	http://www.bostonscientific.com/
510(k) history	58 submissions · 52 cleared · 2001-2026

Boston Scientific is an American biotechnology and biomedical engineering firm headquartered in Marlborough, Massachusetts. The company manufactures medical devices for interventional specialties including cardiology, endoscopy, urology, and oncology. Boston Scientific has received FDA 510(k) clearances from total submissions since 2001. The company maintains active regulatory engagement, with the latest clearance in 2025. Recent cleared devices span cardiovascular, gastroenterology, urology, orthopedic, and general surgery categories, reflecting broad therapeutic focus. ...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k020110/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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