

K042592 INTEMESH SILICONE-COATED SLING AND SURGICAL MESH WITH INHIBIZONE, MODEL 72403304Dec 14, 2004
82 days to decisionK042592 · Product code: **OTN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k042592/>**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 23, 2004
Decision date	Dec 14, 2004
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	American Medical Systems, Inc.
Location	Mchenry, IL, US
Contact	KRISTYN BENSON
510(k) history	72 submissions · 72 cleared · 1979-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k042592/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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