

**K042851 MENTOR OBTAPE TRANS-OBTURATOR SURGICAL KIT**Nov 9, 2004  
25 days to decisionK042851 · Product code: **OTN** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k042851/>**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	Oct 15, 2004
Decision date	Nov 9, 2004
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mentor Corp.</b>
Location	Mchenry, IL, US
Contact	DONNA CRAWFORD
510(k) history	61 submissions · 61 cleared · 1977-2013

Mentor Corp. is a surgical aesthetics and medical device company based in McHenry, US. Now part of Johnson & Johnson MedTech, the brand supplies products to plastic surgeons and specialists worldwide. Mentor has received FDA 510(k) clearances from total submissions since its first clearance in 1977. The company's regulatory record spans General & Plastic Surgery, Gastroenterology & Urology, Obstetrics & Gynecology, and Radiology device categories. The latest clearance was recorded in 2013, reflecting the company's historical significance in surgical device innovation. Men...