

**K913524 SILICONE MALE EXTERNAL CATHETER**Oct 4, 1991  
57 days to decisionK913524 · Product code: **EXJ** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k913524/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Incontinence, Urosheath Type, Sterile (EXJ)
Date received	Aug 8, 1991
Decision date	Oct 4, 1991
Days to decision	57 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Mentor Corp.</b>
Location	Mchenry, IL, US
Contact	BYRON H WICKETT
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...

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