

**K890402 MENTOR CYLINDER PROTECTOR TOOL
(INFLATABLE PENILE)**Aug 3, 1989
191 days to decisionK890402 · Product code: **FAE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k890402/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Penile (FAE)
Date received	Jan 24, 1989
Decision date	Aug 3, 1989
Days to decision	191 days
Third-party review	No

APPLICANT

Company	Mentor Corp.
Location	Mchenry, IL, US
Contact	BYRON 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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