

**K843280 MALLEABLE PENILE PROSTHESIS**Oct 24, 1984  
65 days to decisionK843280 · Product code: **FAE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k843280/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Penile (FAE)
Date received	Aug 20, 1984
Decision date	Oct 24, 1984
Days to decision	65 days
Third-party review	No

**APPLICANT**

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Company	<b>Mentor Corp.</b>
Location	Mchenry, IL, US
Contact	CHRISTINE EMANUEL
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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