FDA 510(k) Premarket Notification

K040959 MENTOR GENESIS PENILE PROSTHESIS

CLEARED

Oct 29, 2004
199 days to decision

K040959 · Product code: **FAE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k040959/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Penile (FAE)
Date received	Apr 13, 2004
Decision date	Oct 29, 2004
Days to decision	199 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Mentor Corp.**
Location	Mchenry, IL, US
Contact	DONNA A 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...