FDA 510(k) Premarket Notification

K905484 ACCU-TEC SYSTEM FOR TISSUE EXPANDER INJECTION PORT

CLEARED

Feb 11, 1991
67 days to decision

K905484 · Product code: **LCJ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k905484/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tissue Expander And Accessories (LCJ)
Date received	Dec 6, 1990
Decision date	Feb 11, 1991
Days to decision	67 days
Third-party review	No

APPLICANT

Company	**Mentor Corp.**
Location	Mchenry, IL, US
Contact	BRYON 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...