

K842883 RADOVAN TISSUE EXPANDERAug 17, 1984
25 days to decisionK842883 · Product code: **LCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k842883/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tissue Expander And Accessories (LCJ)
Date received	Jul 23, 1984
Decision date	Aug 17, 1984
Days to decision	25 days
Third-party review	No

APPLICANT

Company	Mentor Corp.
Location	Mchenry, IL, US
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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