

K962013 MENTOR H/S SILICONE GEL SHEETING FOR SCAR MANAGEMENTAug 22, 1996
91 days to decisionK962013 · Product code: **MDA** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k962013/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone, For Scar Management (MDA)
Date received	May 23, 1996
Decision date	Aug 22, 1996
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mentor Corp.
Location	Mchenry, IL, US
Contact	LYNN BRECKENRIDGE
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...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k962013/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 19, 2026