

K161067 Mirragen Advanced Wound Matrix, 4x4", Mirragen Advanced Wound Matrix, 2x2", Mirragen Advanced Wound Matrix, 1x6"Sep 15, 2016
153 days to decisionK161067 · Product code: **QSZ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k161067/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Absorbable Synthetic Wound Dressing (QSZ)
Date received	Apr 15, 2016
Decision date	Sep 15, 2016
Days to decision	153 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Engineered Tissue Solutions, LLC
Location	Rolla, MO, US
Contact	Mark Borden
510(k) history	1 submissions · 1 cleared · 2016-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161067/> 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 June 2, 2026