

K200918 SurgiWrap FROSTJan 7, 2021
276 days to decisionK200918 · Product code: **FTL** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k200918/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Apr 6, 2020
Decision date	Jan 7, 2021
Days to decision	276 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mast Biosurgery
Location	San Diego, CA, US
Contact	Roel Trip
510(k) history	2 submissions · 2 cleared · 2008-2021

REGULATORY CONSULTANT

Consulting firm	QSR Consulting
Contact	Kenneth K. Kleinhenz

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200918/> 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 27, 2026