

K150676 L-Mesitran Dressing Family II- Soft and TulleDec 23, 2015
282 days to decisionK150676 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k150676/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Mar 16, 2015
Decision date	Dec 23, 2015
Days to decision	282 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Theo Manufacturing BV
Location	Bailey, CO, US
Contact	Monique Gottgens
510(k) history	2 submissions · 2 cleared · 2007-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150676/> 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 3, 2026