

K053613 L-MESITRAN HYDRO, L-MESITRAN BORDER, L-MESITRAN NET, L-MESITRAN ACTIVEJul 25, 2007
575 days to decisionK053613 · Product code: **FRO** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k053613/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Dec 27, 2005
Decision date	Jul 25, 2007
Days to decision	575 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k053613/> 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