

K946245 TIELLE* HYDROPOLYMER DRESSINGApr 11, 1995
110 days to decisionK946245 · Product code: **KMF** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k946245/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Bandage, Liquid (KMF) |
| Date received | Dec 22, 1994 |
| Decision date | Apr 11, 1995 |
| Days to decision | 110 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Johnson & Johnson International |
| Location | New Brunswick, NJ, US |
| Contact | RALPH H LARSEN |
| 510(k) history | 10 submissions · 10 cleared · 1989-1997 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k946245/> 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 21, 2026