

**K801365 KOLD WRAP**Aug 7, 1980  
58 days to decisionK801365 · Product code: **IME** · Physical MedicineSource: <https://www.510kdatabase.net/k801365/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pack, Hot Or Cold, Reusable (IME)
Date received	Jun 10, 1980
Decision date	Aug 7, 1980
Days to decision	58 days
Third-party review	No

**APPLICANT**

---

Company	<b>Romaine, Inc.</b>
Location	Walker, MI, US
510(k) history	1 submissions · 1 cleared · 1980-1980

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k801365/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 1, 2026