

**K841397 BURN BATH**May 18, 1984  
45 days to decisionK841397 · Product code: **ILJ** · Physical MedicineSource: <https://www.510kdatabase.net/k841397/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bath, Hydro-massage (ILJ)
Date received	Apr 3, 1984
Decision date	May 18, 1984
Days to decision	45 days
Third-party review	No

**APPLICANT**

---

Company	<b>Setma, Inc.</b>
Location	Mchenry, IL, US
510(k) history	7 submissions · 7 cleared · 1984-1986

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k841397/> 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 June 30, 2026