

**K963626 9TH WAVE MODELS 400 & 450 ALTERNATING  
PRESSURE MATTRESS**Nov 26, 1996  
76 days to decisionK963626 · Product code: FNM · General Hospital  
Source: <https://www.510kdatabase.net/k963626/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mattress, Air Flotation, Alternating Pressure (FNM)
Date received	Sep 11, 1996
Decision date	Nov 26, 1996
Days to decision	76 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>9th Wave, Inc.</b>
Location	Mt Pleasant, SC, US
Contact	JEAN ROZINT
510(k) history	3 submissions · 3 cleared · 1996-1997

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k963626/> 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 July 6, 2026