

K963620 9TH WAVE MODELS 500 & 550 LOW AIR LOSS SYSTEMSJan 7, 1997
119 days to decisionK963620 · Product code: **FNM** · General Hospital
Source: <https://www.510kdatabase.net/k963620/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mattress, Air Flotation, Alternating Pressure (FNM)
Date received	Sep 10, 1996
Decision date	Jan 7, 1997
Days to decision	119 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k963620/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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