

K811159 DYNASOUND 801May 27, 1981
29 days to decisionK811159 · Product code: **IMI** · Physical MedicineSource: <https://www.510kdatabase.net/k811159/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ultrasonic Diathermy For Use In Applying Therapeutic Deep Heat (IMI)
Date received	Apr 28, 1981
Decision date	May 27, 1981
Days to decision	29 days
Third-party review	No

APPLICANT

Company	Dynawave, Corp.
Location	Mchenry, IL, US
510(k) history	3 submissions · 3 cleared · 1980-1994

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k811159/> 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 June 29, 2026