

K863615 ENTHERMO IRRIGATION UNITDec 16, 1986
91 days to decisionK863615 · Product code: **ETP** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k863615/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Caloric-water (ETP)
Date received	Sep 16, 1986
Decision date	Dec 16, 1986
Days to decision	91 days
Third-party review	No

APPLICANT

Company	Jedmed Instrument Co.
Location	Mchenry, IL, US
Contact	CRAIG RAPP
510(k) history	92 submissions · 91 cleared · 1979-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k863615/>; 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 May 22, 2026