

**K040798 HES ULTRASONIC THERAPY APPLIANCE**Aug 4, 2004  
128 days to decisionK040798 · Product code: **IMI** · Physical MedicineSource: <https://www.510kdatabase.net/k040798/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ultrasonic Diathermy For Use In Applying Therapeutic Deep Heat (IMI)
Date received	Mar 29, 2004
Decision date	Aug 4, 2004
Days to decision	128 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Hwang Sun Enterprise Co., Ltd.</b>
Location	Sound Beach, NY, US
Contact	RICHARD C LANZILLOTTO
510(k) history	2 submissions · 2 cleared · 2004-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k040798/> 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 29, 2026