

**K991613 SW ULTRASOUND, MODELS 331, 311, 333**Dec 8, 2000  
578 days to decisionK991613 · Product code: **IMI** · Physical MedicineSource: <https://www.510kdatabase.net/k991613/>**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	May 10, 1999
Decision date	Dec 8, 2000
Days to decision	578 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Starbene</b>
Location	Cordoba, Pvcia. Cordoba, AR
Contact	JUDITH NITZSCHMAMN
510(k) history	2 submissions · 2 cleared · 2000-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k991613/> 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