

K000084 ENRAF-NONIUS SONOPULS 190 SYSTEMAug 4, 2000
205 days to decisionK000084 · Product code: **IMI** · Physical MedicineSource: <https://www.510kdatabase.net/k000084/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ultrasonic Diathermy For Use In Applying Therapeutic Deep Heat (IMI)
Date received	Jan 12, 2000
Decision date	Aug 4, 2000
Days to decision	205 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Henley Healthcare, Inc.
Location	Sugar Land, TX, US
Contact	REBECCA STOUT
510(k) history	2 submissions · 2 cleared · 2000-2002

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