

**K243112 Curapuls 670**Jun 25, 2025  
268 days to decisionK243112 · Product code: **IMJ** · Physical Medicine  
Source: <https://www.510kdatabase.net/k243112/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diathermy, Shortwave, For Use In Applying Therapeutic Deep Heat (IMJ)
Date received	Sep 30, 2024
Decision date	Jun 25, 2025
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Enraf-Nonius, B.V.</b>
Location	Delft, NL
Contact	Tom Doodkorte
510(k) history	5 submissions · 5 cleared · 2003-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Qara Consulting, LLC</b>
Contact	Scott Blood

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243112/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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