

**K220538 DolorClast Radial**Jul 11, 2022  
136 days to decisionK220538 · Product code: **ISA** · Physical Medicine  
Source: <https://www.510kdatabase.net/k220538/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Therapeutic, Electric (ISA)
Date received	Feb 25, 2022
Decision date	Jul 11, 2022
Days to decision	136 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>E.M.S Electro Medical Systems S.A</b>
Location	North Attleboro, MA, US
Contact	Timothée Deblock
510(k) history	28 submissions · 28 cleared · 2005-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Heyer Regulatory Solutions, LLC</b>
Contact	Sheila Hemeon-Heyer

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220538/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026