

**K223620 Reprive by RegensisTM**May 24, 2023  
170 days to decisionK223620 · Product code: **IMJ** · Physical Medicine  
Source: <https://www.510kdatabase.net/k223620/>**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	Dec 5, 2022
Decision date	May 24, 2023
Days to decision	170 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Regensis Biomedical, Inc.</b>
Location	Scottsdale, AZ, US
Contact	Randy Chavez
510(k) history	4 submissions · 4 cleared · 1997-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223620/> 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 May 27, 2026