

**K202788 Sonomed IV, Sonomed V**Dec 23, 2021  
457 days to decisionK202788 · Product code: **IMI** · Physical Medicine  
Source: <https://www.510kdatabase.net/k202788/>**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	Sep 22, 2020
Decision date	Dec 23, 2021
Days to decision	457 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Carci Industria E Comercio DE Aparelhos Cirurgicos E Orto</b>
Location	Sao Paulo, BR
Contact	Orlando Orlandi
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Pr Servicos Regulatorios Administrativos Ltda</b>
Contact	Bruno Milhoci

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202788/> 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 25, 2026