

K252396 Cryo Sport 2.0 (AVA 501)May 29, 2026
302 days to decisionK252396 · Product code: **IRP** · Physical Medicine
Source: <https://www.510kdatabase.net/k252396/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	Jul 31, 2025
Decision date	May 29, 2026
Days to decision	302 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Avanutri Equipamentos DE Saúde
Location	Tres Rios, BR
Contact	Daiana Vieira
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Bhp Consulting, LLC
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.netDevice record: <https://www.510kdatabase.net/k252396/> Data sourced from FDA 510(k) public records (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. - Generated June 7, 2026