

K243572 Game Ready system (550500-04)Jan 31, 2025
74 days to decisionK243572 · Product code: **IRP** · Physical Medicine
Source: <https://www.510kdatabase.net/k243572/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	Nov 18, 2024
Decision date	Jan 31, 2025
Days to decision	74 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement
Other names	Game Ready Control Unit (550550-04); Game Ready Full Leg Boot Wrap - Medium (590923-04); Game Ready Full Leg Boot Wrap - Large (590922-04); Game Ready C-T Spine Wrap (590502-04); Game Ready Half Leg Boot (590906-04); Game Ready Back Wrap (590500-04); Game Ready Hand/Wrist Wrap (590811-04); Game Ready Flexed Elbow Wrap (590903-04); Game Ready Straight Elbow Wrap (590200-04); Game Ready Shoulder Wrap, Medium, Right (590422-04); Game Ready Shoulder Wrap, La

APPLICANT

Company	Avanos Medical, Inc.
Location	Alpharetta, GA, US
Contact	Dana Goussev
510(k) history	8 submissions · 8 cleared · 2019-2025

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