

K192114 Game Ready GRPro 2.1 SystemOct 29, 2019
84 days to decisionK192114 · Product code: **IRP** · Physical Medicine
Source: <https://www.510kdatabase.net/k192114/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	Aug 6, 2019
Decision date	Oct 29, 2019
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cool Systems, Inc. (Db a Game Ready)
Location	Concord, CA, US
Contact	Natalie Kennel
510(k) history	2 submissions · 2 cleared · 2017-2019

REGULATORY CONSULTANT

Consulting firm	Njk & Associates
Contact	Natalie Kennel

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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