



July 19, 2019

Federal Communications Commission
FCC ID: 2AOQW-FG-0053

Re: FCC Certification Documentation Requirements (G103645080) - Permissive Change for the Radial Medical Cirvo Compression System

To whom it may concern:

Radial Medical is submitting the permissive changes for the current Cirvo device (FG 00432) that are detailed below.

Summary Comparison to Previous Device (FG/FA-0054):

The following table provides a summary of substantial equivalence between the previous device and the current device (FG-00432). The current device has the same intended use and substantially equivalent technological characteristics that do not raise different questions of safety or effectiveness.

Comparison to Previous Device and Current Device

Key Attributes	Previous Device (G3)	Current Device (C2)
Name	Radial Medical Compression System	Cirvo Compression System
Part Number	FG-0054	FG-0432
Target Population	Patients requiring compression therapy.	Patients requiring compression therapy.
Where Used	Hospital, physician office, and home	Hospital, physician office, and home
Anatomical Site	Calf	Calf
User	Physician and patient	Physician and patient
Power Source	Rechargeable battery	Rechargeable battery
Pressure Delivered	40 – 60 mmHg	40 – 60 mmHg
Mechanical Property	2 servo motors	1 servo motor
Pressure sensor	Force sensor resistor (FSR) – 2 FSRs	1 FSR
Electrical Property	2 Printed circuit boards (signal and power PCBs)	1 consolidated PCB (combined signal and power)
Bluetooth Property	Bluetooth circuitry	Bluetooth circuitry
Enclosure material	2 enclosures	1 enclosure (no material change)
Foam cover	No foam cover (exposed enclosure)	Foam cover
Vibrator	No vibrator	Vibrator as an enhanced feature (secondary). Pressure delivery is the primary function of the compression device.
Charging Method	Wireless inductive charging unit using 12V power adapter	Direct plug-in charging using 12V power adapter

Please let us know if you need any additional information.

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