

## 510 (k) SUMMARY: EMS-1C / EMS-2C

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**Contact Person:** Philip D. Norvell, Chief Engineer

- **Proprietary Names:** EMS-1C and EMS-2C
- **Common Name:** Electrical Muscle/Neuromuscular Stimulator
- **Classification Name:** Stimulator, Muscle, Powered

**Background:** The EMS-2A is capable of both Interrupted Direct Current and Pulsed stimulation. The EMS-1A is identical, except that it is only capable of Interrupted D.C. stimulation. Both models have been marketed by Med Labs, since 1969. We are planning the release of two new versions of these instruments, at as early a date as possible. The new versions will be called the EMS-1C and the EMS-2C.

**Description:** The new versions will incorporate three changes, all of which we believe to be minor, and may be accurately described as technological improvements.

1. First, we wish to change the type of battery from a 67.5 volt to a 9 volt. This will make battery replacement much easier and much less expensive for our customers. Initially, several companies made the 67.5 volt battery, but now, it is only available from Eveready. In addition, Eveready has recently increased the price of this battery by about 80%. It is now more cost-effective to use a D.C. to D.C. Converter powered by an inexpensive and readily available 9 volt battery.

This change is for the convenience of our customers, and will not have any effect on the specifications, safety, or efficacy.

2. Second, we are changing the electrode connectors from .080" pin plugs and pin jacks to a safer design as recommended by the F.D.A.. The new connector will be a 3.5mm right angle phone plug, which is physically too large to fit into a standard 120 volt outlet. In an F.D.A. letter from Susan Alpert, M.D., Ph.D., Director, Office of Device Evaluation, dated February 15, 1995, manufacturers were told that it is not necessary to wait for 510(k) approval before making this change. However, we should notify the F.D.A. when we make the change.
3. The third change will add a new circuit to limit the on-time (Pulse Width) and duty cycle in the Interrupted D.C. (Galvanic) mode. This will prevent a user from exceeding the recommended on-time. This in turn, will limit the RMS current and power dissipated in the patients skin and surrounding tissue, and therefore keep the skin irritation to a minimum.

This change will also have no effect on efficacy, since it will simply prevent the user from delivering a wider pulse than is recommended in the current instructions. It will, however, improve safety and comfort.

NOTE: With the EMS-1A and EMS-2A, the pulse width and duty cycle in the Interrupted D.C. mode are manually controlled (by how long the user presses the switch). Our current instruction manual states that the push-button switch should be pressed for about 1/4 second.

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**Substantial Equivalence:** These units are substantially equivalent in efficacy and safety to the Powered Muscle Stimulators which MED LABS, Inc. currently markets, since they are based on the same equipment, specifications, indications, and contraindications, with improved technology.

<b>COMPANY</b>	<b>PRODUCT</b>	<b>510K NUMBER</b>	<b>NOTES</b>
MED LABS, Inc.	EMS-1/EMS-1A	“Grandfathered”	Pre-amendment Device
MED LABS, Inc.	EMS-2/EMS-2A	“Grandfathered”	Pre-amendment Device

We request that the EMS-1C and EMS-2C be accepted as equal in safety and effectiveness to the above equipment.

If you have any questions or require further documentation, please feel free to call us at (805) 968-2486.