

# SunDance

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Topeka, KS 66619

May 2, 2000

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Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
Rm. 1-23  
12420 Parklawn Drive  
Rockville, MD 20857

## CITIZEN PETITION

The undersigned submits this petition under 21CFR Part 898 (Medical Devices; Establishment of a Performance Standard for Electrode Lead Wires and Patient Cables) as adopted under The Safe Medical Devices Act of 1990 (21 U.S.C. 321-394) and the Medical Device Amendments of 1976 to request an administrative action from the Commissioner of Food and Drugs.

### A. Action Requested

We hereby request that the Commissioner of Food and Drugs allow a variance in the Effective Date for Compliance for the patient cables used with the specific products listed below:

1. Patient cables used with Omnistim 500, Omnistim FX2, and Neuroprobe 500 neuromuscular electrical stimulators, manufactured by Accelerated Care Plus, LLC.

Specifically, we request that a variance be granted to allow clinicians to continue using existing cables already in their possession for up to 90 days (until August 7, 2000) while compliant cables and adapters are distributed to them. We are not requesting a variance to allow continued manufacture or distribution of non-compliant cables.

### B. Statement of Grounds

This variance in the Effective Date for Compliance is requested for the following reasons:

1. It was originally expected that adapters and compliant cables compatible with ACP neuromuscular stimulators designed before the adoption of this performance standard would be available from several third party suppliers. However, adapters and cables designed by unrelated third parties have generally been found unsuitable for use with the ACP devices named in this petition because of the close spacing and recessed mounting of patient cable jacks.
2. Adapters and compliant patient cables for use with the neuromuscular electrical stimulators listed above have been designed by ACP and are in production, but have not yet been distributed to all existing users. This distribution is an ongoing task that will take a few months to identify, notify and supply all existing users of ACP devices.
3. The current, non-compliant cable design does not pose the macro-shock hazard addressed by the performance standard:
  - The 1/4" Stereo Phone Plug is too large to insert into a power receptacle, extension cord or power cord.
  - The mating electrodes used with these cables have insulated, female, "dead-front" connectors that protect the patient against inadvertent contact with either electrical power or ground.

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4. Due to the nature and application of clinical neuromuscular electrical stimulators (NMES), the micro-shock hazard introduced by a disconnected patient cable coming into contact with electrical ground is extremely small:
  - The intended use of NMES is to deliver electrical energy to the patient. Therefore, outputs are electrically isolated and other electrical connections to the patient are contraindicated.
  - Cardiovascular disease and pacemakers are specific contraindications for NMES.
  - These devices are rarely, if ever, used intra-operatively or on patients connected to physiologic monitors.
5. It is detrimental to patient care and clinical outcome to withhold treatment because compliant cables have not yet been delivered to the clinician.

In summary, we believe the clinical benefits to patients of allowing clinicians to continue using existing patient cables with ACP neuromuscular stimulators while compliant cables and adapters are being distributed far outweigh any potential electrical safety risks.

C. Environmental Impact

The petitioner is unaware of any environmental impact associated with the requested variance.

D. Economic Impact

N/A

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Michael R. Ronayne  
Director of Regulatory Affairs

Accelerated Care Plus, LLC  
6700 SW Topeka Blvd.  
Topeka, KS 66619

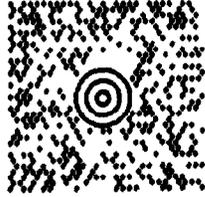
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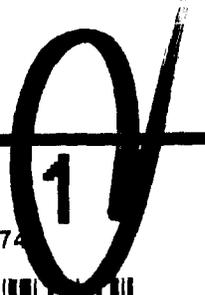
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 FOOD AND DRUG ADMINISTRATION  
 DEPT. OF HEALTH AND HUMAN SERVICES  
 1061  
 5630 FISHERS LANE  
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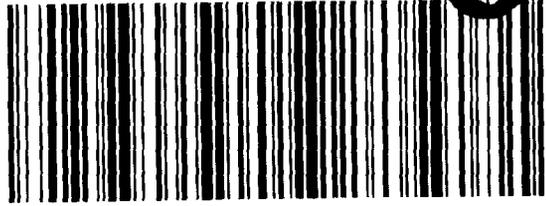


MD 2070-04



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