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Tuesday, April 23, 2002

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

Citizen Petition

The undersigned submits this petition under 21 CFR 898.14 of the Federal Food and Drug Administration, Department of Health and Human Services to request the Commissioner of Food and Drugs to issue an exemption.

Action Requested

Our request is for exemption to the 898.12 performance standard listed below:

Any connector in a lead having a conductive connection to a patient shall be constructed in such a manner that no conductive connection of that part of the said connector which is remote from the patient can contact earth or possibly hazardous voltages.

Statement of Grounds

Hako-Med distributes a vasopneumatic device (VacuPulls/VasoPulse 510k K981116) that works in conjunction with an electromedical therapy device. Vacuum hoses connect to the vasopneumatic device and to flexible suction cups that have electrodes built-in. Some of the hoses have a wire that runs current

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from the electromedical device that the vasopneumatic device is connected to the patient. The hose also provides suction from the vasopneumatic device that fix the cups to the patient. The ends of the hoses that insert into the vasopneumatic device have exposed metal and would seem to fail the 898.12 performance standard. However, the suction power from the vasopneumatic device is what makes the vacuum cups (electrode) stay in contact with the patient. It is not possible to place the electrodes on the patient without the tubes being inserted into the operating vasopneumatic device. Once the ends of the hoses are inserted into the vasopneumatic device there are no exposed metal parts to come in contact with any outside power source. Additionally, when the hoses are removed or the vasopneumatic device is turned off the electrodes immediately fall off of the patient.

It may be possible for the person administering the treatment to fix the cups to the patient with some other mechanical aid such as tape or strapping. This would already be a serious error on the behalf of the therapist and then to attempt to insert the tubes into an AC outlet would be considered murder. However, if needed we can add a remark in the operating manual that no straps, tape, or other mechanical aids are allowed to fix the vacuum cups to the skin.

The device PalJet 510K K973663 uses the same vacuum hose from the same manufacturer that Hako-Med utilizes and has already been granted an exemption based on this same reason.

Environmental Impact

There would be no environmental impact.



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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.

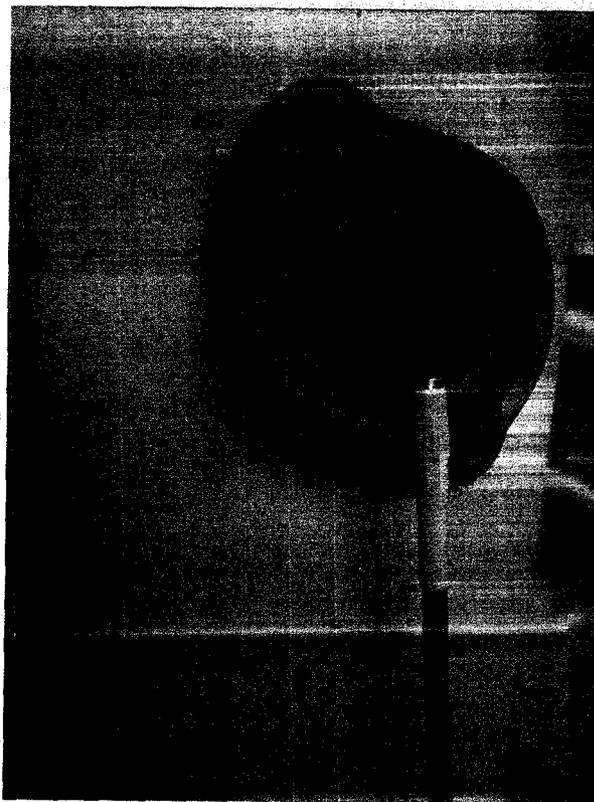
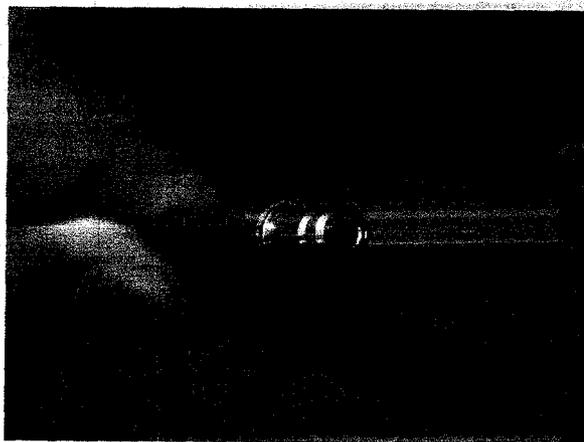
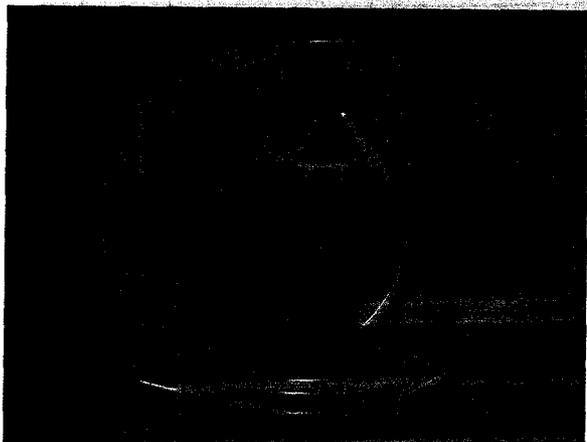
A handwritten signature in black ink, appearing to read "Kai Hansjurgens", written over a horizontal line.

Kai Hansjurgens
President
Hako-Med
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(808) 596-4529

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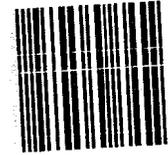
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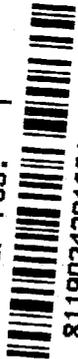
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