



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Michael Bergelson, Ph.D.
President
PACEART Associates, L.P.
81 Two Bridges Road
Building 2
Fairfield, New Jersey 07004

Re: Docket No. 99P-2548/CP 1

Dear Dr. Bergelson:

This responds to your letter, dated July 23, 1999, in which you request a three year extension to the May, 11, 1998, effective date of compliance with the Performance Standard for Electrode Lead Wires and Patient Cables, as it applies to PACEART's "Heart Access Plus" Cardiac Event Recorder. Accordingly, you request an effective date of May 11, 2001, for compliance with the standard. We regret the delay associated with our response to you on this matter.

Based on the technical information you provided, we understand that approximately one hundred (100) PACEART "Heart Access Plus" Cardiac Event Recorders distributed prior to May 11, 1998, are designed so that the electrode lead wires must be inserted into the event recorder to record a cardiac event. The patient depresses a button on the event recorder when cardiac symptoms are experienced to record an electrocardiograph. To transmit the electrocardiograph by telephone, the electrode lead wires must be removed from the event recorder. The electrode lead wires must also be removed when the event recorder is programmed. When the electrode lead wires are re-attached to the event recorder, all stored electrocardiographs are erased. These design features preclude the use of an adapter.

FDA is granting a temporary variance for PACEART "Heart Access Plus" Cardiac Event Recorders distributed prior to May 11, 1998, because adapters cannot be used to convert these devices. Non-compliant electrode lead wires that were received by customers prior to May 11, 1998, and intended for use with the "Heart Access Plus" Cardiac Event Recorders, may continue to be used with those event recorders until May 11, 2001. In addition, you or a third party may provide non-compliant replacement electrode lead wires to your customers for their specific event recorders. However, prior to May 11, 2001, each customer must discontinue use of those non-compliant electrode lead wires. After May 11, 2001, all "Heart Access Plus" Cardiac Event Recorders must accept electrode lead wires that comply with the standard. The extended transition period

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provides customers sufficient time to replace or retrofit their event recorders in order to comply with the performance standard.

As a condition of this action, the FDA requests that you notify your customers regarding this temporary variance. Please prepare a notification letter to your existing "Heart Access Plus" Cardiac Event Recorder customers that notifies them of the specific provisions of this variance, any available retrofit options, and their obligation to be in full compliance with the performance standard by May 11, 2001. The letter should be issued to your customers within 45 days of your receipt of this letter. A copy of the letter should be submitted to Mr. Kent A. Berthold at FDA, Office of Compliance, HFZ-341, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

I trust that this response fully addresses your concerns. If additional information is required, please contact Kent A. Berthold in the Office of Compliance, at (301) 594-4648.

Sincerely yours,

A handwritten signature in cursive script, reading "Linda S. Kahan".

Linda S. Kahan
Deputy Director for Regulations and Policy
Center for Devices and Radiological Health

Biological Fluids: The guidance recommends (page 5, paragraph 3, line 8) the use of plasma and/or serum. It should be expanded to include blood as well.

CYP4502D6 or CYP4502C19: The guidance recommends consideration of the metabolic status of the patient for drugs metabolized by these two enzymes but does not address what will be an acceptable approach. Phenotyping may not be useful as in hepatic impairment a patient may become a “poor metabolizer”.

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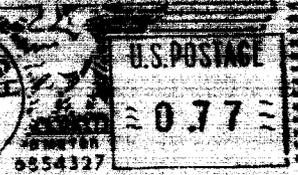
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HFA-224
HFA-305 (Docket #99P-2548/CP 1)
HFR-CE300
HFZ-1
HFZ-3
HFZ-215 (JSheehan, MHanna, Files)
HFZ-300
HFZ-305 (Precedent File)
HFZ-340 (3)
HFZ-341 (Berthold, Firm File)
HFZ-450 (Barbara Zimmerman)

Tracking

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WIRE, PACEART, E



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