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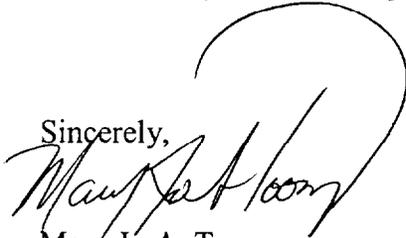
Sharon Murrain-Ellerbe
Office of Compliance
HFZ-340
Center for Devices and Radiological Health
2094 Gaither Road
Rockville, MD 20850

RE: Citizen Petition 00P-0442

Dear Ms. Murrain-Ellerbe,

Enclosed, please find a copy of the letter to our customers notifying them that Citizen Petition 00P-0042 was granted. Per instructions, this letter was mailed to customers within 15 days of our receipt of the letter that granted us the variance.

Sincerely,



Mary Jo A. Toomey
Product Manager, Obstetrics
Kendall-LTP
(413) 593-8203
mtoomey@ludlowhq.com

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Healthcare

KENDALL-LTP 2 Ludlow Park Drive Chicopee MA 01021 800-669-1009

April 21, 2000

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Dear Materials Manager,

We are pleased to inform you that Citizen Petition 00P-0042, a request for a temporary variance on behalf of health care providers from compliance with the Performance Standard for Electrode Lead Wire and Patient Cables (21 CFR 898) was granted by the Food and Drug Administration.

The variance applies ONLY to Kendall-LTP manufactured fetal scalp electrodes stocked in user facilities before May 9, 2000. This means that our customers can continue to use in-house stock of FSE 1000 series and FSE 2020 fetal scalp electrodes until August 8, 2000. By August 9, you will be obligated to comply with the Performance Standard.

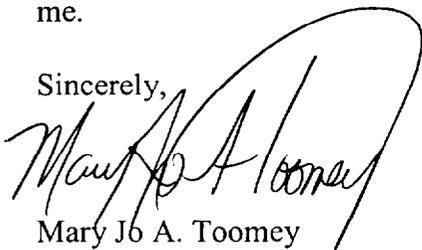
The variance will ensure a smooth transition into fetal monitoring using the Safelinc™ FSE system. Thus, providing you have adequate inventory of the FSE 1000 series and FSE 2020 electrode, you may convert at any time during the 3-month window from May 9 to August 8, 2000. This takes pressure off of you, our customer.

Kendall-LTP is currently in the process of manufacturing the Safelinc™ FSE System cables, attachment pads and fetal scalp electrodes. We will begin shipping the Safelinc™ FSE System in early May. However, due to the quantity of product and cables required by our customers, it will take three months to ensure all orders are filled. The Safelinc™ FSE System is fully in compliance with the Performance Standard.

Please ensure that you have enough stock, in your inventory, of FSE 1000 series or FSE 2020s prior to May 9, 2000, as we will not ship these products after May 8. If you need to order more products or discuss the Safelinc FSE System, please contact your Kendall-LTP sales representative at 1-800-669-1009.

If you have any questions, or require further clarification, please do not hesitate to contact me.

Sincerely,



Mary Jo A. Toomey
Product Manager, Obstetrics
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