El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con un Informe de Seguridad asociado a:

NOMBRE DEL DISPOSITIVO MÉDICO	Procesador de Tejidos LEICA
NO. IDENTIFICACIÓN RISARH	I1509-456
REFERENCIAS DEL DISPOSITIVO MEDICO	ASP200 y ASP300S, con seriales 5259, 5260, 5264, 5266, 5267, 5272, 5273, 5289, 5301, 5310, 5348, 5349, 5356, 5366, 5381, 5385, 5386, 5387, 5388, 5398, 5401, 5403, 5407, 5416, 5426, 5434, 5435, 5446, 5530, 5562, 5609, 5610, 5612, 5663, 5670, 5673, 5682, 5693, 5706, 5724, 5725, 5734, 5737, 5794, 5796, 5798, 5799, 5804, 5807, 5815, 5871, 5873, 5874, 5875, 5886, 5889, 5909, 5926, 5929, 5946, 5947, 5948, 5955, 5956, 5962, 5965, 5977, 6000, 6015, 6021, 6040, 6041, 6042, 6045, 6046, 6062, 6115, 6131, 6149
REGISTRO SANITARIO	2014DM-0012120
INDICACIONES Y USO ESTABLECIDOS	Solo el personal calificado debe utilizar el procesador de tejidos. El equipo ha sido diseñado de tal modo que funciona a prueba de fallos - tanto en lo que se refiere al usuario, como a las muestras a procesar - siempre que el usuario cumpla en todo momento con las instrucciones del manual de usuario. El equipo ha sido diseñado para las siguientes aplicaciones en laboratorio: • fijación, • deshidratación, • infiltración en parafina de muestras histológicas.
NOMBRE DEL FABRICANTE	Leica Biosystems Nussloch Gmbh
DESCRIPCION DEL PROBLEMA	El fabricante establece que el cableado interno de la clavija de la alarma remota en los dispositivos médicos referenciados puede ser incorrecta, lo que puede causar que el mando a distancia no funcione correctamente en caso de fallas del instrumento, la perdida de la alarma podría conducir a un mal procesamiento de la muestra, lo que podría conllevar a que se presenten re-intervenciones y potencialmente eventos adversos sobre el paciente.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	29 de Septiembre de 2015

RECOMENDACIÓN:

En caso de identificar la existencia del producto mencionado anteriormente comuníquese con su proveedor quien determinara las acciones que se llevaran a cabo.

Es importante mantener un estado de alerta, realizando un seguimiento permanente a los productos que se fabrican y/o comercializan en el país, divulgando la información de seguridad respectiva entre los profesionales de la salud que realizan uso de estos recursos tecnológicos.

Para mayor información comuníquese al teléfono 2948700 extensión 3880 en Bogotá, ó al correo electrónico tecnovigilancia@invima.gov.co

ANEXO 1

[High Priority] - A24833 01 : Leica—Model ASP200S and ASP300S Tissue Processors: Faulty Internal Wiring May Prevent Remote Alarm from Functioning during Instrument Failure

Medical Device Ongoing Action

Published: Wednesday, September 23, 2015

UMDNS Terms:

- Tissue Processors [15190]

Product Identifier:
Tissue Processors: (1) Model ASP200S, (2) Model ASP300S *[Capital Equipment]*
Serial Nos.: 5259, 5260, 5264, 5266, 5267, 5272, 5273, 5289, 5301, 5310, 5348, 5349, 5356, 5366, 5381, 5385, 5386, 5387, 5388, 5398, 5401, 5403, 5407, 5416, 5426, 5434, 5435, 5446, 5530, 5562, 5609, 5610, 5612, 5663, 5670, 5673, 5682, 5693, 5706, 5724, 5725, 5734, 5737, 5794, 5796, 5798, 5799, 5804, 5807, 5815, 5871, 5873, 5874, 5875, 5886, 5889, 5909, 5926, 5929, 5946, 5947, 5948, 5955, 5956, 5962, 5965, 5977, 6000, 6015, 6021, 6040, 6041, 6042, 6045, 6046, 6062, 6115, 6131, 6149

Geographic Regions: (Impact in specific regions has not been identified or ruled out at the time of this posting), Worldwide

Manufacturer(s): Leica Microsystems Inc 1700 Leider Ln, Buffalo Grove, IL 60089, United States

Suggested Distribution: Clinical/Biomedical Engineering, Clinical Laboratory/Pathology

Summary:
This Alert provides additional information based on FDA Center for Devices and Radiological Health (CDRH) source material regarding Alert Accession No. A24833 . FDA's CDRH states that the manufacturer initiated a recall by Urgent Medical Device Recall Notification letter dated August 4, 2015. Additional information is provided in the Geographic Regions field (see bolded information).

Problem:
[August 10, 2015]
In a July 28, 2015, Urgent Field Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), Leica states that the internal wiring to the remote alarm plug in the above tissue processors may be incorrect, potentially causing the remote alarm to not function properly in the case of instrument failure. Leica further states that if instrument failure occurs during processing, a missed alarm could lead to suboptimal processing and may necessitate re-biopsy of the patient. The manufacturer has not confirmed the information in the source material.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the July 28, 2015, Urgent Field Safety Notice letter and/or the August 4, 2015, Urgent Medical Device Recall Notification letter and Response Form from Leica. The following actions are those listed in Alert Accession No. A24833 . Leica recommends that users do not use the remote alarm function until the problem has been corrected. Contact your Leica local representative to arrange for a service appointment to correct the internal wiring on your tissue processor and to check the remote alarm function. Complete the response form, and return it to Leica using the instructions on the form. Notify all relevant personnel at your facility of the information in the letter, and forward a copy of the letter to any facility to which you have further distributed product.

For Further Information:
Leica
Website: Click here

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Leica Biosystems: ASP300S (14047643515) [online]. London: Department of Health; 2015 Aug 3 [cited 2015 Aug 5]. (Field safety notice; reference no. 2015/007/028/291/006). Available from Internet: here .
- United States. Food and Drug Administration. Center for Devices and Radiological Health. Class 3 device recall Leica Microsystems Inc. [online]. 2015 Sep 17 [cited 2015 Sep 21]. Available from Internet: Click here .

Comments:

- This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert. For additional information regarding the format of this alert, refer to our HDA Format Guide .

Source(s):

- 2015 Sep 21. FDA CDRH Database. Class III. Z-2779-2015 Download
- 2015 Sep 21. MHRA FSN. 2015/007/028/291/006 Download
- 2015 Sep 21. MHRA FSN. July 28, 2015, Leica letter (includes reply form) Download