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	Citómetro de flujo BECKMAN
NO. IDENTIFICACIÓN RISARH	I1610-425
REFERENCIAS DEL DISPOSITIVO MEDICO	AQUIOS CL - B30166, seriales AY03004, AY20032, AY25038, AY47063, AY47071, AY51072, AY51075, AZ12027, AZ12030, AZ12033, AZ15038, AZ15044, AZ19046, AZ19047, AZ19052.
REGISTRO SANITARIO	2016DM-0014667
INDICACIONES Y USO ESTABLECIDOS	Citómetro de flujo para diagnóstico in vitro.
NOMBRE DEL FABRICANTE	Beckman Coulter Ireland Inc Beckman Coulter Inc
DESCRIPCION DEL PROBLEMA	El fabricante afirma que el uso del carro de reactivos en los dispositivos referenciados puede llevar a una mala alineación del carrusel y daños a la sonda de preparación, conllevando a que se presenten retrasos en el análisis de las muestras.
FUENTE	Anexo
FECHA DE NOTIFICACION	07 de Octubre de 2016

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

[High Priority] - A27327 : Beckman Coulter—AQUIOS CL Flow Cytometer Systems: Use of Reagent Carousel May Lead to Carousel Misalignment and Damage to Prep Probe

Medical Device Ongoing Action

Published: Monday, October 3, 2016

UMDNS Terms:

- Cytometers, Automated [16582]

Product Identifier:
AQUIOS CL Flow Cytometer Systems *[Capital Equipment]*
Catalog No. B30166; Serial Nos.: AY03004, AY20032, AY25038, AY47063, AY47071, AY51072, AY51075, AZ12027, AZ12030, AZ12033, AZ15038, AZ15044, AZ19046, AZ19047, AZ19052
148 units distributed (12 in the U.S., 136 outside the U.S.)

Geographic Regions: (Impact in additional regions has not been identified or ruled out at the time of this posting), Angola, Australia, Belgium, Botswana, Canada, Chile, Colombia, Czech Republic, Denmark, Finland, France, Germany, Ghana, Israel, Italy, Malaysia, Namibia, The Netherlands, Panama, Poland, Romania, Slovakia, South Africa, Spain, Sweden, Switzerland, U.K., Uganda, U.S., Zambia

Manufacturer(s): Beckman Coulter Inc 250 S Kraemer Blvd, Brea, CA 92821-6232, United States

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

Problem:
FDA's Center for Devices and Radiological Health (CDRH) states that use of the reagent carousel on the above systems may lead to misalignment of the carousel and damage to the prep probe. FDA's CDRH also states that the manufacturer initiated a recall by Urgent Medical Device Recall letter dated September 6, 2016. The manufacturer has not confirmed the information provided in the source material.

Action Needed:
Identify any affected systems in your inventory. If you have affected systems, verify that you have received the September 6, 2016, Urgent Medical Device Recall letter and Response Form from Beckman Coulter. Complete the Response Form, and return it to Beckman Coulter using the instructions on the form.

For Further Information:
Beckman Coulter customer support center or Beckman Coulter local representative
Tel.: (800) 269-0333 (U.S. and Canada) Website: Click here

References:

- United States. Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall Aquios CL flow cytometer [online]. 2016 Sep 28 [cited 2016 Sep 29]. 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):

- 2016 Sep 29. FDA CDRH Database. Class II. Z-2900-2016 Download