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	VITROS Sistema De Química Clínica
NO. IDENTIFICACIÓN RISARH	I1402-90
REFERENCIAS DEL DISPOSITIVO MEDICO	VITROS 250 y VITROS 350
REGISTRO SANITARIO	INVIMA 2007DM-0001234
INDICACIONES Y USO ESTABLECIDOS	El producto está indicado para el análisis de pruebas in vitro.
NOMBRE DEL FABRICANTE	Ortho Clinical Diagnostics Inc.
DESCRIPCION DEL PROBLEMA	Informa que las matrices de mezcla pueden ocasionar errores de software y sobre los resultados obtenidos, conllevando a que se presenten potencialmente eventos adversos sobre el paciente.
FUENTE	Anexo
FECHA DE NOTIFICACION	24 de Febrero de 2014

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

A21818 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: February 20, 2014

UMDNS Terms:
- Analyzers, Laboratory, Clinical Chemistry/Immunoassay [20821]
- Software, Laboratory Analysis [26801]

Suggested Distribution:
- Clinical Laboratory/Pathology
- Materials Management
- Clinical/Biomedical Engineering
- Information Technology

Geographic Regions:
- (Impact in additional regions has not been identified or ruled out at the time of this posting)
- Australia
- Brazil
- Canada
- Chile
- China
- Colombia
- France
- Germany
- India
- Italy
- Japan
- Mexico
- Panama
- Puerto Rico
- Singapore
- Spain
- U.K.
- U.S.
- Venezuela

Ortho Clinical Diagnostics—VITROS Mixing Cup Arrays Used with VITROS 250 and 350 Chemistry Systems: May Cause Software Error

Product Identifier:
VITROS Mixing Cup Arrays used with the following VITROS Chemistry Systems: (1) 250, (2) 350 [Consumable, Capital Equipment]
Mixing Cup Array Product No. 1631779

VITROS Chemistry Systems:	Model Nos.:	Product Nos.:
250	3332	8132086
350	3330	6802153

Manufacturer:
- Ortho-Clinical Diagnostics Inc100 Indigo Creek Dr, Rochester, NY 14626, United States

Problem:
FDA's Center for Devices and Radiological Health (CDRH) states that the above mixing cup arrays may cause a software error on the above systems. FDA's CDRH also states that the manufacturer initiated a corrective action by Important Product Correction Notification letter dated October 10, 2013. The manufacturer has not confirmed the information provided in the source material.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the October 10, 2013, Important Product Correction Notification letter and confirmation of receipt form from Ortho Clinical Diagnostics. Complete the confirmation of receipt form, and return it to Ortho Clinical Diagnostics using the information on the form.

For Further Information:
OCD customer technical support department
Tel.: (800) 421-3311

Website: Click here

References:
- United States. Food and Drug Administration. Center for Devices and Radiological Health. Medical device recalls: Class 2 recall—VITROS 250/350 mixing cup array [online]. 2014 Feb 10 [cited 2014 Feb 13]. Available from Internet: Click here.

Comment:
- 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):
- 2014 Feb 13. FDA CDRH Database. Class II. Z-0968-2014