El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con un Retiro de Producto del Mercado asociado a:

NOMBRE DEL DISPOSITIVO MÉDICO	Película Radiográfica Intraoral Dental.
NO. IDENTIFICACIÓN RISARH	R1408-344
REFERENCIAS DEL DISPOSITIVO MEDICO	INSIGHT y Ultra Speed, referencias 8110785 y 8348658 respectivamente, lotes específicos
REGISTRO SANITARIO	2008DM-0002288
INDICACIONES Y USO ESTABLECIDOS	Obtención de imagen radiográfica dental intraoral.
NOMBRE DEL FABRICANTE	Carestream Health, Inc Caretream Healt, Inc Carestream Health, Inc Soluciones Medicas Exportación S. de R.L de C.V Carestream Health, Inc
DESCRIPCION DEL PROBLEMA	El fabricante determinó que el punto indicador en el etiquetado exterior puede estar colocado de manera incorrecta con respecto a la ubicación del punto en relieve en la película, conllevando a que se generen posibles retrasos en la atención de los pacientes
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	25 de Agosto 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

A22818 - Normal Priority Medical Device Alert

Medical Device Ongoing Action
Updated: August 14, 2014
UMDNS Terms:
- X-Ray Film, Dental [14482]

Suggested Distribution:
- Dentistry/Oral Surgery
- Diagnostic Imaging
- Materials Management

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

Carestream—Kodak INSIGHT and Ultra-Speed Dental Film: Orientation Dot on Outer Packaging May Be Incorrectly Positioned

Product Identifier:

Kodak Dental Film:	Reference Nos.:	Lot Nos.:
INSIGHT	811 0785	53801303, 53801303-1, 53901201, 54601201, 54601201-1
Ultra-Speed	834 8658	333012 part unknown, 33301201, 33301202, 33301203, 34301501

[Consumable]

Manufacturer:
- Carestream Health Inc150 Verona St, Rochester, NY 14608, United States

Problem: FDA's Center for Devices and Radiological Health (CDRH) states that the indicator dot on the above film packet's outer printed paper labeling may be incorrectly positioned relative to the location of the raised dot on the film. FDA's CDRH also states that the manufacturer initiated a recall by letter on July 2, 2014. 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 July 2, 2014, letter from Carestream. Complete an inventory of goods and return it to Carestream.
For Further Information:
Carestream customer care center
Tel.: (800) 933-8031
Website: Click here

References:
United States.

- Food and Drug Administration. Center for Devices and Radiological Health. Medical device recalls: Class 3 device recall INSIGHT dental film [online]. 2014 Aug 1 [cited 2014 Aug 5]. Available from Internet: Click here.
- Food and Drug Administration. Center for Devices and Radiological Health. Medical device recalls: Class 3 device recall Ultraspeed dental film [online]. 2014 Aug 1 [cited 2014 Aug 5]. 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 Aug 5. FDA CDRH Database. Class III. Z2142/2143-2014