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	Sistema de Radiocirugía Robótica CYBERKNIFE
NO. IDENTIFICACIÓN RISARH	I1402-65
REFERENCIAS DEL DISPOSITIVO MEDICO	CYBERKNIFE ACCURAY
REGISTRO SANITARIO	INVIMA 2009EBC-0003732
INDICACIONES Y USO ESTABLECIDOS	El sistema de radiocirugía robótica CYBERKNIFE es una alternativa no invasiva a la cirugía para el tratamiento de tumores cancerosos y no cancerosos en cualquier lugar del cuerpo, como por ejemplo la próstata, el pulmón, el cerebro, la columna vertebral, el hígado, el páncreas y el riñón. El tratamiento –que administra haces de radiación mediante un acelerador lineal en dosis elevadas a los tumores con una precisión extrema– ofrece nuevas esperanzas a los pacientes de todo el mundo. Los sistemas CYBERKNIFE están previstos para brindar planeación del tratamiento y radiocirugía esterotactica y radioterapia de precisión guiados por imágenes para tumores, lesiones y condiciones en cualquier lugar del cuerpo cuando se indica el tratamiento con radiación. Estos sistemas pueden usarse para tratar astrocitoma, glioma, tumores de la base del cráneo, metastasis, (cerebral y ósea), carcinoma nasofaringeo, meningioma, neuroma acústico, malformaciones arterevenosas y cavernosas, neuralgia trigeminal y tumores del cuello, pulmón.
NOMBRE DEL FABRICANTE	Accuray Incorporated.
DESCRIPCION DEL PROBLEMA	Afirma que el conjunto del brazo articulado utilizado para el montaje de la cámara puede desprenderse y provocar que esta se caiga, conllevando a que se presenten potencialmente eventos adversos serios sobre el paciente o el operador.
FUENTE	Anexo
FECHA DE NOTIFICACION	14 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

A21770 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: February 13, 2014

UMDNS Terms:
- Stereotactic Systems, Image-Guided, Radiosurgical, Linear Accelerator [26629]

Suggested Distribution:
- Clinical/Biomedical Engineering
- Radiation Oncology/Medical Physics
- Facilities/Building Management

Geographic Regions:
- Worldwide

Accuray—Synchrony Boom Arm Mounting Assembly Used with CyberKnife Systems: Assembly Joint May Detach and Fall

Product Identifier:

Synchrony Arm Mounting Assembly used with CyberKnife Systems *[Capital Equipment]*
Part No.: 054000-001; Serial Nos.: C0006, C0007, C0008, C0012, C0013, C0014, C0019, C0020, C0022, C0030, C0032, C0033, C0037, C0038, C0041, C0042, C0045, C0046, C0047, C0048, C0049, C0051, C0052, C0053, C0054, C0055, C0056, C0057, C0058, C0059, C0060, C0061, C0062, C0063, C0064, C0065, C0067, C0068, C0070, C0071, C0072, C0073, C0074, C0075, C0076, C0077, C0078, C0079, C0080, C0084, C0085, C0086, C0087, C0088, C0089, C0090, C0091, C0092, C0093, C0094, C0095, C0097, C0098, C0099, C0100, C0101, C0102, C0103, C0105, C0106, C0107, C0108, C0109, C0110, C0111, C0112, C0113, C0114, C0115, C0117, C0118, C0119, C0120, C0121, C0122, C0123, C0124, C0125, C0126, C0127, C0128, C0130, C0131, C0132, C0133, C0134, C0135, C0136, C0137, C0138, C0139, C0140, C0141, C0143, C0144, C0145, C0146, C0147, C0148, C0149, C0150, C0151, C0152, C0154, C0155, C0157, C0158, C0159, C0160, C0161, C0162, C0163, C0165, C0166, C0168, C0169, C0170, C0171, C0173, C0174, C0175, C0176, C0177, C0178, C0179, C0180, C0181, C0182, C0183, C0184, C0185, C0186, C0187, C0188, C0189, C0190, C0191, C0192, C0193, C0194, C0195, C0196, C0197, C0198, C0199, C0200, C0201, C0202, C0203, C0204, C0205, C0206, C0207, C0208, C0209, C0210, C0211, C0212, C0213, C0214, C0215, C0216, C0217, C0218, C0219, C0220, C0221, C0222, C0223, C0224, C0225, C0226, C0227, C0228, C0229, C0230, C0231, C0232, C0233, C0234, C0235, C0236, C0237, C0238, C0239, C0240, C0241, C0242, C0243, C0244, C0245, C0246, C0247, C0248, C0249, C0251, C0252, C0253, C0254, C0255, C0256, C0257, C0258, C0259, C0260, C0261, C0262, C0263, C0264, C0265, C0266, C0267, C0268, C0269, C0270, C0271, C0272, C0273, C0274, C0275, C0276, C0277, C0278, C0279, C0280, C0281, C0282, C0283, C0284, C0285, C0286, C0287, C0288, C0289, C0290, C0291, C0292, C0293, C0294, C0295, C0296, C0297, C0298, C0299, C0300, C0301, C0302, C0303, C0304, C0305, C0306, C0307, C0308, C0309, C0310, C0312, C0313, C0314, C0315, C0316, C0317, C0319, C0320, C0321, C0322, C0323, C0324, C0325, C0326, C0327, C0329, C0330, C0331, C0332, C0333, C0334, C0335, C0336, C0337, C0338, C0339, C0340, C0341, C0342, C0343, C0344, C0345, C0347, C0348, C0349, C0351

302 units distributed

Manufacturer:
- Accuray Inc1240 Deming Way, Madison, WI, 53717, United States

Problem:
In a January 14, 2014, Urgent Device Correction letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), Accuray states that a joint on the boom arm mounting assembly for the above cameras may detach and cause the camera to fall, potentially resuting in serious injury to the patient or user. FDA's center for Devices and Radiological Health (CDRH) states that the manufacturer initiated a correction by Urgent Medical Device Correction letter dated January 14, 2014.

Action Needed:
Identify any affected product in your facility. If you have affected product, verify that you have received the January 14, 2014, Urgent Device Correction letter and acknowledgment of notification form from Accuray. Complete and return the acknowledgement of notification form using the instructions provided in the form. Inspect the joints of the boom arm mounting assembly using the instructions provided in the letter. If any twisting motion or loose connections are suspected in the threaded joints of the boom arm mounting assembly, call the Accuray customer support department. If the boom arm mounting assembly is secure, no other immediate action

is required. Accuray will contact your facitilty to arrange to secure the mounting assembly.

For Further Information:

Accuray
U.S.
Tel.: (877) 668-8667 (USA)
Outside the U.S.
Tel.: (408) 716-4700
Website: Click here

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Accuray Incorporated. Radiotherapy Cyber Knife. CyberKnife robotic radiosurgery system [online]. London: Department of Health; 2014 Jan 31 [cited 2014 Feb 11]. (Field safety notice; reference no. 2014/001/027/081/020). Available from Internet: Click here.
- United States. Food and Drug Administration. Center for Devices and Radiological Health. Medical Device Recalls: Class 2 recall—Accuray CyberKnife robotic radiosurgery system [online]. 2014 Jan 27 [cited 2014 Feb 11]. 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 10. MHRA FSN. MHRA Reference No.: 2014/001/027/081/020
- 2014 Feb 10. FDA CDRH Database. Class II. Z-0828-2014
- 2014 Feb 10. MHRA FSN. Accuray letter submitted to MHRA (includes reply form)
- 2014 Feb 12. Manufacturer. The manufacturer confirmed the information provided in the source material.