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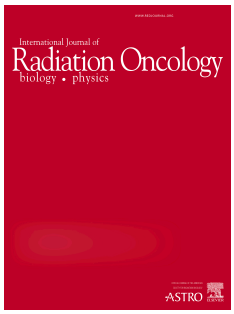

Medical Device Recalls in Radiation Oncology: Analysis of U.S. Food and Drug Administration Data, 2002-2015

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Medical Device Recalls in Radiation Oncology: Analysis of U.S. Food and Drug Administration Data, 2002-2015

Short title: Device recalls in radiation oncology

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Summary: FDA recalls among radiation oncology devices peaked in 2011 and mostly reflected software issues. These recalls differ significantly from other devices in cause of recall, recall class (severity), quantity in commerce, and time from 510(k) market clearance to recall. The field should demand better design of these systems as well as improved regulatory requirements, software quality efforts, and enhanced post-market surveillance.

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