State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

X-Strahl Recalls X-Ray and Photoelectric Therapy Systems for Software Issue

Recall Date	Product Description	Recalling Firm	Recall Reason
10/26/2021	**Concerto User Interface Software** Provided with the following systems: (1) Xstrahl 100 Electronic Brachytherapy - 100kV Superficial X-Ray Therapy System; (2) Xstrahl 150 Electronic Brachytherapy - 150kV Superficial X-Ray Therapy System; (3) Xstrahl 200 - 225kV Superficial / Orthovoltage X-Ray Therapy System; (4) Xstrahl 300 - 300kV Orthovoltage X-Ray Therapy System; (5) Xstrahl X 80 Photoelectric Therapy System	**X-Strahl Limited.** Walsall, United Kingdom	If a saved treatment plan with 2 opposing beams is edited prior to approval, then Beam 2 is not updated with the changed parameters upon selecting save, resulting in error messages during the treatment and possible mis-treatment.

Recall Class	Product Identification	Distribution	Affected Dates
II	**Concerto User Interface Software** V2.0, V2.1, and V2.2 when 2 opposing beam treatment plans are used	25 systems Nationwide including California	April 2021 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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