

1/13/2026

Device Name	Smartray® GLX 0.1
Indication for Use:	<p>The Smartray® GLX 0.1 is a medical device indicated to assist healthcare professionals in achieving orthogonal precise and consistent Cervicocranial positioning with control of all degrees of Head rotation.</p> <p>The system provides real-time, AI-generated visual guidance to support required head alignment and reporting. The final positioning and X-ray exposure decisions remain solely with the healthcare provider. The device does not modify or control the X-ray machine, nor does it interpret or analyze medical images for diagnostic purposes.</p>
Intended Use:	Smartray® GLX 0.1 is for use in general X-ray radiology on people suspected of having symptoms of Cervicocranial Instability (CCI).
Directions for Use	As per User Manuals.
Manufacturer	The Smartxray, LLC Ave. Constitucion con Carr. PR 27, San Juan, PR 00928, USA
CAUTION:	Federal Law restricts this device to sale by or on the order of a physician, dentist, or other practitioners licensed by the law of the State in which the person practices to use or order to use of the device.