

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:	<p>Smartray® GLX 0.1 is for use in general X-ray radiology on people suspected of having symptoms of Cervicocranial Instability (CCI).</p>
Directions for Use	As per User Manuals.
Manufacturer	<p>The Smartxray, LLC Ave. Constitucion con Carr. PR 27, San Juan, PR 00928, USA</p>
CAUTION:	<p>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.</p>