

7/13/2025

Device Name	Smartray® GLX 0.1
Intended Use:	The Smartray® GLX 0.1 is a medical device designed to assist healthcare professionals in achieving precise and consistent patient head positioning in pure orthogonal view during neutral and weight bearing X-ray imaging studies of the Cervicocranial Junction (CCJ). The system provides real-time, AI-generated visual guidance to support pure orthogonal head alignment. 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.
Indication for Use:	Smartray® GLX 0.1 provides real-time AI-assisted visual guidance designed for consistent and precise pure orthogonal head positioning required for Cervicocranial Junction X-ray imaging studies. The system assists healthcare professionals in creating, directing, maintaining and storing head alignment. It does not physically touch the patient for stabilizing or controlling head movement.
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.