

MAY 14 1997

K970947

**510(k) Summary**

March 25, 1997

**Submitter:** Omega Medical Imaging, Inc. 675 Hickman Circle, Sanford, FL 32771.  
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**Device Name:** B-350 Isocentric Ceiling Mounted C-Positioner.

**Classification Name:** System, Fluoroscopic, Image Intensified, All Types.

**Common/Usual Name:** C-Arm

**Substantially Equivalent Devices:** Fisher's *PEGASUS* Ceiling Mounted Cardiac Positioner, Philips *DIAGNOST* Lateral C-Arm, Fisher's *ARIEL* Ceiling Mounted C-Arm, and Fisher's *CPS* Ceiling Mounted Imaging System.

**Description:** The B-350 Ceiling Mounted C-Positioner is a device intended to hold an X-Ray tube and an image intensifier 180° apart in a "C" configuration for the purpose of performing general purpose diagnostic fluoroscopic procedures.

The C-Positioner allows variable positioning of the X-Ray tube/Image Intensifier from 30 degrees Left Anterior Oblique (LAO) to 120 degrees Left Posterior Oblique (LPO). The device will maintain isocenter throughout its full range of motorized movement. The entire assembly is mounted to a set of ceiling rails with a detent provided to lock the unit into place for use in creating a common isocenter between the Anterior/Posterior (A/P) and lateral planes. A microswitch controlled interlock system independently prevents X-Ray exposure anywhere outside the detent position.

**Intended Use:** To support the Diagnostic Source Assembly & the Image Receptor used in performing general purpose diagnostic fluoroscopic procedures.

**Summary of Technological Characteristics:** The B-350 Ceiling Mounted C-Positioner has the same technological characteristics as the predicate devices. The B-350 and the predicate devices all have the same intended use: to support the X-Ray tube (Diagnostic Source Assembly) and the Image Intensifier (Image Receptor) directly opposite each other with some variation in the distance from the X-Ray tube to the Image Receptor (SID), for diagnostic fluoroscopic procedures. The only differences in the devices are market driven variables such as the SID, arc rotation for different procedures, and the ability to rotate about the ceiling axis. The above devices are essentially all ceiling suspended C-Arms with some variations depending on user preference. The Omega B-350 Ceiling Mounted C-Positioner (C-Arm) is substantially equivalent to the predicate devices as well as any number of other Ceiling Mounted C-Arms that have been legally marketed in the U.S. for many years.