

**K093816 DIGITAL RADIOGRAPHY SYSTEM, MODELS GALAXY
900 AND 1600**Oct 5, 2010
298 days to decisionK093816 · Product code: **KPR** · Radiology
Source: <https://www.510kdatabase.net/k093816/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Dec 11, 2009
Decision date	Oct 5, 2010
Days to decision	298 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medien International Co, Ltd.
Location	Echo, OR, US
Contact	CHARLES MACK
510(k) history	3 submissions · 3 cleared · 2010-2017

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