

**K834611 SINGUL-XR RP NON SCREEN MED. FILM**Feb 21, 1984  
63 days to decisionK834611 · Product code: **IWZ** · Radiology  
Source: <https://www.510kdatabase.net/k834611/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Film, Radiographic (IWZ)
Date received	Dec 20, 1983
Decision date	Feb 21, 1984
Days to decision	63 days
Third-party review	No

**APPLICANT**

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Company	<b>Cea America Corp.</b>
Location	Mchenry, IL, US
510(k) history	5 submissions · 5 cleared · 1984-1996

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Device record: <https://www.510kdatabase.net/k834611/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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