

**K920505 AMERLEX-M EXTENDED RANGE HUMAN CHORIONIC GONADATR**Mar 23, 1992  
47 days to decisionK920505 · Product code: JHI · Chemistry  
Source: <https://www.510kdatabase.net/k920505/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Feb 5, 1992
Decision date	Mar 23, 1992
Days to decision	47 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Eastman Kodak Company</b>
Location	Mchenry, IL, US
Contact	YVONNE ADAIR
Website	<a href="http://www.kodak.com">http://www.kodak.com</a>
510(k) history	238 submissions · 238 cleared · 1977-2006

Eastman Kodak Company is a diversified imaging and materials manufacturer headquartered in McHenry, US. The company has a long history in advanced materials, chemicals, and imaging technologies. Eastman Kodak maintains a significant regulatory history in medical imaging devices. The company received FDA 510(k) clearances from total submissions, with clearances spanning from 1977 to 2006. The company's cleared devices focused primarily on radiology and medical imaging systems, including digital radiography systems, picture archiving and communication systems (PACS), and re...

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Device record: <https://www.510kdatabase.net/k920505/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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