

**K970154 KODAK EKTASIAN HG FILM (EHG-15)**Apr 4, 1997  
78 days to decisionK970154 · Product code: **IWZ** · Radiology  
Source: <https://www.510kdatabase.net/k970154/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Film, Radiographic (IWZ)           |
| Date received         | Jan 16, 1997                       |
| Decision date         | Apr 4, 1997                        |
| Days to decision      | 78 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|---|
| Company        | <b>Eastman Kodak Company</b>                            |
| Location       | McHenry, IL, US   |
| Contact        | MARIA DURKIN  |
| 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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