

**K944254 OKTAS STEREO VIEWING SYSTEM**Nov 30, 1994  
91 days to decisionK944254 · Product code: **FET** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k944254/>**SUBMISSION DETAILS**

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|                       |                                                                           |
|-----------------------|---------------------------------------------------------------------------|
| Decision              | Substantially Equivalent (Cleared)                                        |
| Submission type       | Traditional                                                               |
| Device classification | Endoscopic Video Imaging System/component, Gastroenterology-urology (FET) |
| Date received         | Aug 31, 1994                                                              |
| Decision date         | Nov 30, 1994                                                              |
| Days to decision      | 91 days                                                                   |
| Third-party review    | No                                                                        |
| Summary / Statement   | Statement                                                                 |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Oktas</b>                          |
| Location       | Ashland, MA, US                       |
| Contact        | KEN HORI                              |
| 510(k) history | 7 submissions · 7 cleared · 1994-1997 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k944254/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated July 1, 2026