

**K191615 Huvitz Imaging System**Jul 18, 2019  
30 days to decisionK191615 · Product code: **NFJ** · Ophthalmic  
Source: <https://www.510kdatabase.net/k191615/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Image Management, Ophthalmic (NFJ)
Date received	Jun 18, 2019
Decision date	Jul 18, 2019
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Huvitz Co., Ltd.</b>
Location	Flintville, TN, US
Contact	Hyung Min Heo
510(k) history	6 submissions · 6 cleared · 2008-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191615/> 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 May 26, 2026