

K161829 Huvitz Imaging SystemApr 6, 2017
275 days to decisionK161829 · Product code: **NFJ** · Ophthalmic
Source: <https://www.510kdatabase.net/k161829/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Management, Ophthalmic (NFJ)
Date received	Jul 5, 2016
Decision date	Apr 6, 2017
Days to decision	275 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Huvitz Co., Ltd.
Location	Flintville, TN, US
Contact	KIM EUN-JO
510(k) history	6 submissions · 6 cleared · 2008-2023

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