

**K190954 Fundus Camera**Jan 22, 2020  
286 days to decisionK190954 · Product code: **HKI** · Ophthalmic  
Source: <https://www.510kdatabase.net/k190954/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Apr 11, 2019
Decision date	Jan 22, 2020
Days to decision	286 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Chongqing Bio Newvision Medical Equipment , Ltd.</b>
Location	Chongqing, CN
Contact	Wang Hao
510(k) history	1 submissions · 1 cleared · 2020-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Beijing Believe-Med Technology Service Co., Ltd.</b>
Contact	Ray Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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