

**K192880 InferRead Lung CT.AI**Jul 2, 2020  
267 days to decisionK192880 · Product code: **OEB** · Radiology  
Source: <https://www.510kdatabase.net/k192880/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lung Computed Tomography System, Computer-aided Detection (OEB)
Date received	Oct 9, 2019
Decision date	Jul 2, 2020
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Beijing Infervision Technology Co., Ltd.</b>
Location	Beijing, CN
Contact	Xiaoyan Fan
510(k) history	1 submissions · 1 cleared · 2020-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Infervision Us, Inc.</b>
Contact	Matt Deng

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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