

K182643 IRIS 1.0 SystemFeb 22, 2019
151 days to decisionK182643 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k182643/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 24, 2018
Decision date	Feb 22, 2019
Days to decision	151 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Intuitive Surgical
Location	Suonyvale, CA, US
Contact	Crystal Ong
Website	http://www.intuitivesurgical.com
510(k) history	16 submissions · 15 cleared · 2014-2024

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