

K183388 JADE Mobile X-RayFeb 5, 2019
61 days to decisionK183388 · Product code: **IZL** · Radiology
Source: <https://www.510kdatabase.net/k183388/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Dec 6, 2018
Decision date	Feb 5, 2019
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	DRGEM Corporation
Location	Echo, OR, US
Contact	Ki-Nam Yang
510(k) history	13 submissions · 13 cleared · 2010-2025

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