

K183292 Topaz Mobile DR SystemMay 15, 2019
170 days to decisionK183292 · Product code: **IZL** · Radiology
Source: <https://www.510kdatabase.net/k183292/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Nov 26, 2018
Decision date	May 15, 2019
Days to decision	170 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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