

K190096 R2GATEJun 26, 2019
155 days to decisionK190096 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k190096/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jan 22, 2019
Decision date	Jun 26, 2019
Days to decision	155 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Megagen Implant Co., Ltd.
Location	Santa Fe Springs, CA, US
Contact	HyeJin Jung
510(k) history	31 submissions · 31 cleared · 2008-2025

REGULATORY CONSULTANT

Consulting firm	Mtechgroup
Contact	Dave Kim

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

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