FDA 510(k) Premarket Notification

K223909 R2GATE Lite TM

CLEARED

Oct 20, 2023
295 days to decision

K223909 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k223909/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Dec 29, 2022
Decision date	Oct 20, 2023
Days to decision	295 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	Tae Gyoun Lee
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