FDA 510(k) Premarket Notification

K220779 XD

CLEARED

Apr 15, 2022
29 days to decision

K220779 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k220779/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Mar 17, 2022
Decision date	Apr 15, 2022
Days to decision	29 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Mirada Medical, Ltd.**
Location	Oxford, Oxfordshire, GB
Contact	Adam Taylor
510(k) history	8 submissions · 8 cleared · 2010-2022

REGULATORY CONSULTANT

Consulting firm	**Third Party Review Group, LLC**
Contact	Dave Yungvirt

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