

K220779 XDApr 15, 2022
29 days to decisionK220779 · 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

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