FDA 510(k) Premarket Notification

**CLEARED**

# K221072 TRUEdraw Lancing Device, Mini Lancing Device

Oct 18, 2022
189 days to decision

K221072 · Product code: **QRL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k221072/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Multiple Use Blood Lancet For Single Patient Use Only (QRL) |
| Date received | Apr 12, 2022 |
| Decision date | Oct 18, 2022 |
| Days to decision | 189 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Trividia Health** |
| Location | Fort Lauderdale, FL, US |
| Contact | Jacqueline Davis |
| 510(k) history | 1 submissions · 1 cleared · 2022-2022 |