FDA 510(k) Premarket Notification

# K231531 Pediarity™

**CLEARED**

Dec 21, 2023
209 days to decision

K231531 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k231531/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Oximeter (DQA) |
| Date received | May 26, 2023 |
| Decision date | Dec 21, 2023 |
| Days to decision | 209 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Hinlab, Inc.** |
| Location | Lewes, DE, US |
| Contact | Denys-Michel de Larouziere |
| 510(k) history | 1 submissions · 1 cleared · 2023-2023 |

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k231531/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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