FDA 510(k) Premarket Notification

# K212783 ProstatID

**CLEARED**

Jul 8, 2022
310 days to decision

K212783 · Product code: **QDQ** · Radiology
Source: https://www.510kdatabase.net/k212783/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Radiological Computer Assisted Detection/diagnosis Software For Lesions Suspicious For Cancer (QDQ) |
| Date received | Sep 1, 2021 |
| Decision date | Jul 8, 2022 |
| Days to decision | 310 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

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|---|---|
| Company | **Scanmed, LLC** |
| Location | Omaha, NE, US |
| Contact | Randall Jones |
| 510(k) history | 1 submissions · 1 cleared · 2022-2022 |