

K260714 MammoScreen® (5)

Jun 26, 2026
113 days to decision

K260714 · Product code: **QDQ** · Radiology
Source: <https://www.510kdatabase.net/k260714/>

SUBMISSION DETAILS

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Radiological Computer Assisted Detection/diagnosis Software For Lesions Suspicious For Cancer (QDQ) |
| Date received | Mar 5, 2026 |
| Decision date | Jun 26, 2026 |
| Days to decision | 113 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Therapixel |
| Location | Valbonne, FR |
| Contact | Shalyna Long Bansropun |
| 510(k) history | 7 submissions · 7 cleared · 2020-2026 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k260714/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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