

K243084 BioTraceIO Precision (2.0)Dec 27, 2024
88 days to decisionK243084 · Product code: **QZL** · Radiology
Source: <https://www.510kdatabase.net/k243084/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Post-ablation Tissue Response Prediction Software (QZL) |
| Date received | Sep 30, 2024 |
| Decision date | Dec 27, 2024 |
| Days to decision | 88 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Techsomed Medical Technologies , Ltd. |
| Location | Rehovot, IL |
| Contact | Dalia Dickman |
| 510(k) history | 2 submissions · 1 cleared · 2023-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243084/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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