

**K241907 Anovo Surgical System (model 6N)**Oct 2, 2024  
93 days to decisionK241907 · Product code: **QNM** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k241907/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional   |
| Device classification | Mountable Electromechanical Surgical System For Transluminal Approaches (QNM) |
| Date received         | Jul 1, 2024   |
| Decision date         | Oct 2, 2024   |
| Days to decision      | 93 days   |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Momentis Surgical , Ltd.</b>       |
| Location       | Or Yehuda, IL                         |
| Contact        | Maya Leib Shlomo                      |
| 510(k) history | 8 submissions · 7 cleared · 2021-2025 |

**CLINICAL EVIDENCE - NCT06457971****Anovo Surgical System in Ventral Hernia**

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|-------------------|--|
| Status            | Recruiting - <i>No results published to ClinicalTrials.gov</i> |
| Enrollment        | 50 patients (estimated)  |
| Study sites       | 2 sites  |
| Condition studied | Ventral Hernia   |
| Primary purpose   | Treatment  |
| Study type        | Interventional   |
| Study design      | Single group   |
| Masking           | Open label   |
| Completion date   | Dec 1, 2025  |
| Sponsor           | Momentis Surgical (Industry)                                   |

**Primary outcome****Rate of Conversion****Secondary outcome****IntraOperative Procedural Outcomes - AE and SADE**Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT06457971](https://clinicaltrials.gov/study/NCT06457971)