

K222226 EONFeb 17, 2023
207 days to decisionK222226 · Product code: **PKT** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k222226/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Laser For Disruption Of Adipocyte Cells For Aesthetic Use (PKT) |
| Date received | Jul 25, 2022 |
| Decision date | Feb 17, 2023 |
| Days to decision | 207 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Dominion Aesthetic Technologies, Inc. |
| Location | Winter Park, FL, US |
| Contact | Ahmed Mohammed |
| 510(k) history | 3 submissions · 3 cleared · 2019-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222226/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026