

K252781 MSFX MIKRON PEEK CAGESDec 19, 2025
108 days to decisionK252781 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k252781/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Intervertebral Fusion Device With Bone Graft, Cervical (ODP) |
| Date received | Sep 2, 2025 |
| Decision date | Dec 19, 2025 |
| Days to decision | 108 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Mikron Makina Sanayi VE Tic. Ltd. Sti. |
| Location | Yenimahalle, TR |
| Contact | Mustafa Ekiz |
| 510(k) history | 1 submissions · 1 cleared · 2025-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252781/> 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 14, 2026