

K193320 KMTI Tesera SA Anterior Lumbar Interbody Fusion (ALIF) SystemFeb 4, 2020
64 days to decisionK193320 · Product code: **OVD** · Orthopedic
Source: <https://www.510kdatabase.net/k193320/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD) |
| Date received | Dec 2, 2019 |
| Decision date | Feb 4, 2020 |
| Days to decision | 64 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Kyocera Medical Technologies, Inc. |
| Location | Redlands, CA, US |
| Contact | Anthony DeBenedictis |
| 510(k) history | 15 submissions · 15 cleared · 2020-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193320/>. 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