

K181432 ProVectra 3D Prime with VistaSoftAug 2, 2018
62 days to decisionK181432 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k181432/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | X-ray, Tomography, Computed, Dental (OAS) |
| Date received | Jun 1, 2018 |
| Decision date | Aug 2, 2018 |
| Days to decision | 62 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Durr Dental SE |
| Location | Bietigheim-Bissingen, DE |
| Contact | Oliver Lange |
| 510(k) history | 9 submissions · 9 cleared · 2018-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181432/> 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