

K213326 VisionX 3.0Nov 2, 2021
28 days to decisionK213326 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k213326/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received | Oct 5, 2021 |
| Decision date | Nov 2, 2021 |
| Days to decision | 28 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | 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 |

REGULATORY CONSULTANT

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|-----------------|------------------------------|
| Consulting firm | Kamm & Associates |
| Contact | Daniel Kamm |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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