

K043325 ZOOMCAM LD-10 INTRAORAL CAMERA AND ACCESSORIESFeb 11, 2005
71 days to decisionK043325 · Product code: **EIA** · Dental
Source: <https://www.510kdatabase.net/k043325/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Unit, Operative Dental (EIA) |
| Date received | Dec 2, 2004 |
| Decision date | Feb 11, 2005 |
| Days to decision | 71 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Rolence Enterprise, Inc. |
| Location | Chungi, TW |
| Contact | STERLING CHENG |
| 510(k) history | 2 submissions · 2 cleared · 2004-2005 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k043325/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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