

**K140060 DIGITAL DENTAL INTRA ORAL SENSOR, HDI 2000,
HDI 2000A**May 13, 2014
123 days to decisionK140060 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k140060/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Solid State X-ray Imager (flat Panel/digital Imager) (MQB) |
| Date received | Jan 10, 2014 |
| Decision date | May 13, 2014 |
| Days to decision | 123 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Rayence Co., Ltd. |
| Location | Houston, TX, US |
| Contact | DAVE KIM |
| 510(k) history | 38 submissions · 38 cleared · 2011-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k140060/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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