

K140056 DIGITAL DENTAL INTRA ORAL SENSORMay 13, 2014
123 days to decisionK140056 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k140056/>**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 |
| Other names | HDI 1000, HDI 1000A |

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/k140056/> 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 15, 2026