FDA 510(k) Premarket Notification

# K092171 VOLUX, DIGITAL EXTRAORAL SOURCE X-RAY SYSTEM

**CLEARED**

Apr 26, 2010
279 days to decision

K092171 · Product code: **MUH** · Radiology
Source: https://www.510kdatabase.net/k092171/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, X-ray, Extraoral Source, Digital (MUH) |
| Date received | Jul 21, 2009 |
| Decision date | Apr 26, 2010 |
| Days to decision | 279 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Genoray Co., Ltd.** |
| Location | Flintville, TN, US |
| Contact | JAE KIM |
| 510(k) history | 24 submissions · 24 cleared · 2007-2026 |

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k092171/ 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 17, 2026