

K231449 Portable X-ray System Model Ray98(P)Jul 13, 2023
56 days to decisionK231449 · Product code: **EHD** · Radiology
Source: <https://www.510kdatabase.net/k231449/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Unit, X-ray, Extraoral With Timer (EHD) |
| Date received | May 18, 2023 |
| Decision date | Jul 13, 2023 |
| Days to decision | 56 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Ningbo Runyes Medical Instrument Co., Ltd. |
| Location | Ningbo Zhejiang, CN |
| Contact | Weiqiong Fang |
| 510(k) history | 2 submissions · 2 cleared · 2023-2026 |

REGULATORY CONSULTANT

| | |
|-----------------|-----------------------|
| Consulting firm | 510K FDA, Inc. |
| Contact | W. Lee Strong |

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231449/> 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 25, 2026