

K251038 Digital Radiographic Imaging Acquisition Software - DR (RiasDR)Aug 6, 2025
125 days to decisionK251038 · Product code: LLZ · Radiology
Source: <https://www.510kdatabase.net/k251038/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received | Apr 3, 2025 |
| Decision date | Aug 6, 2025 |
| Days to decision | 125 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Shen Zhen Cambridge-Hit Co., Ltd. |
| Location | Shenzhen, CN |
| Contact | Zhao Ming |
| 510(k) history | 1 submissions · 1 cleared · 2025-2025 |

REGULATORY CONSULTANT

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|-----------------|--|
| Consulting firm | Shenzhen Joyantech Consulting Co., Ltd. |
| Contact | Fu Field |

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

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