

**K232068 HyperLight Portable X-ray Unit**Sep 1, 2023  
51 days to decisionK232068 · Product code: **EHD** · Radiology  
Source: <https://www.510kdatabase.net/k232068/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Jul 12, 2023
Decision date	Sep 1, 2023
Days to decision	51 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Changzhou Sifary Medical Technology Co., Ltd.</b>
Location	Changzhou, CN
Contact	Tao Huan
510(k) history	4 submissions · 4 cleared · 2021-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>510K FDA, Inc.</b>
Contact	W. Lee Strong

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232068/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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