

**K242499 Digital Radiography X-ray System (SONTU100-RAD (E)  
, SONTU300-Mars (E))**Jan 6, 2025  
137 days to decisionK242499 · Product code: **KPR** · Radiology  
Source: <https://www.510kdatabase.net/k242499/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Aug 22, 2024
Decision date	Jan 6, 2025
Days to decision	137 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shenzhen?Sontu?Medical?Imaging?Equipment?Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Xiaomei Lao
510(k) history	1 submissions · 1 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Suzhou Device Innovation Medical Consulting Co., Ltd.</b>
Contact	Mike Gu

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

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