

K242314 Minimally Invasive Prostate Surgery Navigation System(Model:AmaKris SR1-A-2)Sep 11, 2025
402 days to decisionK242314 · Product code: LLZ · Radiology
Source: <https://www.510kdatabase.net/k242314/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Aug 5, 2024
Decision date	Sep 11, 2025
Days to decision	402 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Augment Intelligent Medical System (China) Co., Ltd.
Location	Nanjing, CN
Contact	Yili Liu
510(k) history	2 submissions · 2 cleared · 2022-2025

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