

K243447 Rapid Surgical Plan (RSP-SW-001)Dec 5, 2024
28 days to decisionK243447 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k243447/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Nov 7, 2024
Decision date	Dec 5, 2024
Days to decision	28 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Navbit Pty, Ltd.
Location	Crows Nest, AU
Contact	David Thomson
510(k) history	2 submissions · 2 cleared · 2020-2024

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	Dave Yungvirt

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

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