

K203518 QuicktomeMar 9, 2021
98 days to decisionK203518 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k203518/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Dec 1, 2020
Decision date	Mar 9, 2021
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Omniscient Neurotechnology Pty Ltd (O8t)
Location	Sydney, AU
Contact	Arie Henkin
510(k) history	2 submissions · 2 cleared · 2021-2023

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