

K202847 AccuBrainJan 15, 2021
112 days to decisionK202847 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k202847/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 25, 2020
Decision date	Jan 15, 2021
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Brainnow Medical Technology Limited
Location	Hong Kong, CN
Contact	Junbing Huang
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Qimmiq Medical Consulting Service Co., Ltd.
Contact	You Yijie

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

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