

K182875 DeepCTJul 10, 2019
271 days to decisionK182875 · Product code: **QAS** · Radiology
Source: <https://www.510kdatabase.net/k182875/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	Oct 12, 2018
Decision date	Jul 10, 2019
Days to decision	271 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Deep01 Limited
Location	Taipei City, TW
Contact	William Lai
510(k) history	1 submissions · 1 cleared · 2019-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182875/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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