

K210670 BU-CADDec 21, 2021
291 days to decisionK210670 · Product code: **QDQ** · Radiology
Source: <https://www.510kdatabase.net/k210670/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer Assisted Detection/diagnosis Software For Lesions Suspicious For Cancer (QDQ)
Date received	Mar 5, 2021
Decision date	Dec 21, 2021
Days to decision	291 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Taihao Medical, Inc.
Location	Taipei, TW
Contact	Hsin Hung
510(k) history	4 submissions · 4 cleared · 2016-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210670/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026