

K221568 KOLO Evolution XHD Series Ultrasound Diagnostic SystemSep 12, 2022
104 days to decisionK221568 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k221568/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	May 31, 2022
Decision date	Sep 12, 2022
Days to decision	104 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Kolo Medical (Suzhou) Co., Ltd.
Location	Suzhou, CN
Contact	Mike SU
510(k) history	1 submissions · 1 cleared · 2022-2022

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