

K202785 Resona R9,Resona R9 Exp,Resona R9 Pro,Resona R9S, Nueva R9,Nueva R9 Exp,Nueva R9 Pro,Nueva R9S,Resona 7,Resona 7CV,Resona 7EXP,Resona 7S, Resona 7OB,Resona 7PRO,Imagyn 7,Resona Y Diagnostic Ultrasound System

Apr 8, 2021
198 days to decision

K202785 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k202785/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Sep 22, 2020
Decision date	Apr 8, 2021
Days to decision	198 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Mindray Bio-Meidcal Electronics Co., Ltd.
Location	Great Neck, NY, US
Contact	Ma chao
510(k) history	9 submissions · 9 cleared · 2012-2022

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k202785/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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