FDA 510(k) Premarket Notification

CLEARED

K203391 TE7/TE5/TE7 Max/TE5 Max/TE9 Diagnostic Ultrasound System

Mar 23, 2021
125 days to decision

K203391 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k203391/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Nov 18, 2020
Decision date	Mar 23, 2021
Days to decision	125 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**
Location	Shenzhen, CN
Contact	Ma Chao
Website	https://www.mindray.com
510(k) history	156 submissions · 156 cleared · 2004-2026

Shenzhen Mindray Bio-Medical Electronics Co., Ltd. is a medical technology and solutions supplier headquartered in Shenzhen, China. The company develops diagnostic imaging, patient monitoring, and clinical care devices. Mindray has received FDA 510(k) clearances from total submissions since 2004. The company specializes in diagnostic ultrasound systems and radiology devices, with a strong portfolio spanning general imaging, women's healthcare, cardiology, and liver care applications. Recent clearances include multiple ultrasound system variants and central monitoring plat...