

K200643 Hepatus 7/Hepatus 6/Hepatus 5/Hepatus 7S/Hepatus 6S/Hepatus 5S/Hepatus 7T/Hepatus 6T/Hepatus 5T/Fibrous 7/FibrousJul 24, 2020
135 days to decisionK200643 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k200643/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Mar 11, 2020
Decision date	Jul 24, 2020
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Location	Shenzhen, CN
Contact	Jiang Xiaoyong
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...