

K173595 Shear Wave Quantificational Ultrasound Diagnostic System

Jun 22, 2018
213 days to decisionK173595 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k173595/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Nov 21, 2017
Decision date	Jun 22, 2018
Days to decision	213 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Wuxi Hisky Medical Technologies Co., Ltd.
Location	Wuxi, CN
Contact	Jinhua Shao
510(k) history	5 submissions · 5 cleared · 2018-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k173595/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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