

K190769 Bladder Scanner (Models: M2, M2-W, M1, M1-W)May 22, 2019
57 days to decisionK190769 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k190769/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Mar 26, 2019
Decision date	May 22, 2019
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Suzhou Lischka Medtech Co., Ltd.
Location	Kunshan, CN
Contact	Shi Jing
510(k) history	1 submissions · 1 cleared · 2019-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190769/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026