FDA 510(k) Premarket Notification

K202119 AcuSee AS-P1000 System

CLEARED

Oct 7, 2020
69 days to decision

K202119 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k202119/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Jul 30, 2020
Decision date	Oct 7, 2020
Days to decision	69 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Weipeng (Suzhou) Medical Devices Co., Ltd.**
Location	Suzhou, CN
Contact	Bin Yang
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Springborne Life Sciences**
Contact	Geetha Rao

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k202119/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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