FDA 510(k) Premarket Notification

CLEARED

K221008 HDR Sensor- HDR361 (Size 1), HDR Sensor- HDR461 (Size 2)

Jun 22, 2022
78 days to decision

K221008 · Product code: **MUH** · Radiology
Source: https://www.510kdatabase.net/k221008/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Apr 5, 2022
Decision date	Jun 22, 2022
Days to decision	78 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Shanghai Handy Medical Equipment Co., Ltd.**
Location	Baoshan District, CN
Contact	Marcia Qiu
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**510K FDA, Inc.**
Contact	W. Lee Strong

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/k221008/ 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 May 27, 2026