

K212412 IRIS-XPSep 13, 2021
41 days to decisionK212412 · Product code: **LHQ** · Radiology
Source: <https://www.510kdatabase.net/k212412/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Telethermographic (adjunctive Use) (LHQ)
Date received	Aug 3, 2021
Decision date	Sep 13, 2021
Days to decision	41 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medicore Co., Ltd.
Location	Gangnam-Gu, Seoul, KR
Contact	Kyo-bum Kim
510(k) history	3 submissions · 3 cleared · 2007-2021

REGULATORY CONSULTANT

Consulting firm	Gms Consulting
Contact	DoGyun Lim

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

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