

K221189 OLIZ LTB-1000AAug 29, 2022
126 days to decisionK221189 · Product code: **ILY** · Physical Medicine
Source: <https://www.510kdatabase.net/k221189/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lamp, Infrared, Therapeutic Heating (ILY)
Date received	Apr 25, 2022
Decision date	Aug 29, 2022
Days to decision	126 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ltbio Co., Ltd.
Location	Seongnam-Si, KR
Contact	Min-Ho Kim
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	KMC, Inc.
Contact	Jaden Keum

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

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