

K222656 LDE4 Lancing DeviceNov 23, 2022
82 days to decisionK222656 · Product code: **QRL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k222656/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multiple Use Blood Lancet For Single Patient Use Only (QRL)
Date received	Sep 2, 2022
Decision date	Nov 23, 2022
Days to decision	82 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	I-Sens, Inc.
Location	Seoul, KR
Contact	H.S. Yoo
510(k) history	27 submissions · 27 cleared · 2008-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222656/> 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 13, 2026