FDA 510(k) Premarket Notification

K222656 LDE4 Lancing Device

CLEARED

Nov 23, 2022
82 days to decision

K222656 · Product code: **QRL** · General & Plastic Surgery
Source: 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