

**K193350 Leadtek Fingertip Pulse Oximeter**Apr 27, 2020  
146 days to decisionK193350 · Product code: **DQA** · Anesthesiology  
Source: <https://www.510kdatabase.net/k193350/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Dec 3, 2019
Decision date	Apr 27, 2020
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Leadtek Research, Inc.</b>
Location	New Taipei City, TW
Contact	K. S. Lu
Website	<a href="http://www.leadtek.com.tw/">http://www.leadtek.com.tw/</a>
510(k) history	2 submissions · 2 cleared · 2020-2021

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193350/> 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](http://accessdata.fda.gov). - Generated May 26, 2026