

K183661 ClearEdge Balance SystemOct 22, 2019
299 days to decisionK183661 · Product code: **LXV** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k183661/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Vestibular Analysis (LXV)
Date received	Dec 27, 2018
Decision date	Oct 22, 2019
Days to decision	299 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Quadrant Biosciences
Location	Syracuse, NY, US
Contact	Bryan Greene
510(k) history	1 submissions · 1 cleared · 2019-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183661/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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