

K181886 VivaSight-DL SystemNov 14, 2018
124 days to decisionK181886 · Product code: **CBI** · Anesthesiology
Source: <https://www.510kdatabase.net/k181886/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Tube, Tracheal/bronchial, Differential Ventilation (w/wo Connector) (CBI)
Date received	Jul 13, 2018
Decision date	Nov 14, 2018
Days to decision	124 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Etview , Ltd.
Location	Binyamina, IL
Contact	Yoram Levy
510(k) history	8 submissions · 8 cleared · 2005-2018

REGULATORY CONSULTANT

Consulting firm	Qsite
Contact	Yoram Levy

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181886/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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