

K180162 VivaScope SystemMay 3, 2018
104 days to decisionK180162 · Product code: **PSN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k180162/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Light Based Imaging (PSN)
Date received	Jan 19, 2018
Decision date	May 3, 2018
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Caliber Imaging & Diagnostics, Inc.
Location	Rochester, NY, US
Contact	Joel Radford
510(k) history	1 submissions · 1 cleared · 2018-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180162/> 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 30, 2026