

K210265 VS3 Iridium SytemNov 22, 2021
294 days to decisionK210265 · Product code: **OWN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k210265/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Confocal Optical Imaging (OWN)
Date received	Feb 1, 2021
Decision date	Nov 22, 2021
Days to decision	294 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Visionsense, Ltd.
Location	Washington, DC, US
Contact	Nancy Sauer
510(k) history	13 submissions · 13 cleared · 2008-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210265/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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