

K223020 VS3-Iridium System (VS3-IR)Oct 28, 2022
29 days to decisionK223020 · Product code: **OWN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k223020/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Confocal Optical Imaging (OWN)
Date received	Sep 29, 2022
Decision date	Oct 28, 2022
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223020/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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